Creation Date : 11/08/2022

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
TÜV NORD CERT GmbH Am TÜV 1 45307 Essen Germany	0044	*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0110 - Non-active medical devices for ingestion	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation	quality assurance) EC declaration of conformity (product quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			without medical devices according to Commission Regulation (EU) No 722/2012
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7006 - Medical devices in sterile condition			Including ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, thermic sterilisation with dry heat
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
National Standards Authority of Ireland (NSAI) 1 Swift Square, Northwood, Santry Dublin 9 Ireland	0050	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1107 - Active devices for disinfection and			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1106 - Active dental devices - *MD 1108 - Active rehabilitation devices and active prostheses *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Via Quintiliano, 43 20138 - MILANO Italy	0051	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	exclusion medical devices class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	exclusion medical devices class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	exclusion medical devices class III
		*MD 1100 - General active medical devices	EC type-examination	Annex III	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	EC type-examination	Annex III	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1106 - Active dental devices	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality	Annex III Annex IV Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality	Annex III Annex IV Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
MTIC InterCert S.r.l. Sede Legale: Via G.Leopardi, 14 - Sede Operativa: Via Moscova, 11 20123 - Milano (MI) - 20017 - Rho (MI) Italy	0068	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Excluding class III Medical Devices and hyperbaric chambers
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC verification EC declaration of conformity (full quality assurance system)	Annex IV Annex II Annex V Annex VI	Excluding class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III Medical Devices
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 MÜNCHEN Germany	0123	*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis			
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					peroxide, thermic sterilisation with dry heat, sterilisation with liquid sterilants
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
DEKRA Certification GmbH Handwerkstraße 15 70565 STUTTGART Germany	0124	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation,	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		infusion and haemopheresis	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	EC declaration of conformity (full quality	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Product quality assurance		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany	0197	*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system EC type-examination	Annex II Annex III Annex IV	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC verification Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1403 - Devices for hyperthermia / hypothermia	system EC type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	excluding implants for full replacement of the hip, shoulder, knee

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system EC type-examination	Annex II Annex III Annex IV	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC verification Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding hyperbaric therapy chambers
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	excluding devices for stimulating the brain
		*MD 1100 - General active medical devices	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1104 - Active surgical devices	system EC type-examination EC verification Production quality assurance Product quality assurance	Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex II Annex III Annex IV Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality	Annex III Annex IV Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0105 - Non-active ophthalmologic devices	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system EC type-examination	Annex II Annex III Annex IV	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC verification Production quality assurance Product quality assurance	Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			for active medical devices only
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation by liquid chemical sterilants
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		/utilising software /controlled by software			
DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 FRANKFURT AM MAIN Germany	0297	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1402 - Devices utilising non-ionizing radiation	system Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0105 - Non-active ophthalmologic devices	Production quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance	Annex II Annex V	vascular implants only
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	Full quality assurance system	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Production quality assurance		
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0402 - Dental materials	system Production quality assurance	Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Production quality assurance Product quality assurance	Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS Campezo 1. Edificio 7. 28022 MADRID Spain	0318	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limitated to X-ray medical devices and gamma cameras
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices	EC declaration of conformity (full quality	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1302 - Monitoring devices of vital physiological parameters	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limitated to microwave and magnetotherapy medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Annex III limitated to punture, injection and/or extraction of fluids medical devices
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Annex III limitated to male latex condoms
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for	EC type-examination EC declaration of conformity (full quality	Annex III Annex II Annex V	Annex III limitated to contact lenses care products

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		disinfecting, cleaning, rinsing	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Limitated to stents
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding neurological and neurosurgical implants
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding breast implants
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Limitated to diagnostic medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system)	Annex II	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding infusion pumps for the delivery of medicines
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					(EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma x-ray, electron beam), sterilisation with hydrogen peroxide, thermic sterilisation with dry heat.
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
DEKRA Certification B.V. Meander 1051 / P.O. Box 5185 6825 MJ ARNHEM / 6802 ED ARNHEM Netherlands	0344	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		(IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
ISTITUTO SUPERIORE DI SANITA' Viale Regina Elena, 299 00161 - ROMA Italy	0373	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion,	EC declaration of conformity (full quality assurance system)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		transfusion and dialysis	EC declaration of conformity (production quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	Annex III limited to ophthalmic solutions
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0202 - Non-active orthopaedic implants	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V	Annex III limited to injectable visco-elastic solutions for intra-articular use
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex II Annex V	Annex III limited intradermal fillers
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1104 - Active surgical devices	conformity (full quality assurance system)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC type-examination EC verification	Annex III Annex IV	Limited to accelerator for hadron therapy and related dose delivery system
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam, moist heat sterilisation, radiation sterelisation (gamma, electron beam)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
RISE Research Institutes of Sweden AB Box 857 501 15 BORAS Sweden	0402	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging	EC declaration of conformity (full quality	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1202 - Imaging devices utilising non-ionizing radiation	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants	Full quality assurance	Annex II	Bone-anchored implants for dental

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0203 - Non-active functional implants	system Production quality assurance Product quality assurance	Annex V Annex VI	and cranio-facial reconstruction
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Bone-anchored implants for dental and cranio-facial reconstruction
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
INTERTEK SEMKO AB	0413	*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
Torshamnsgatan 43 Box 1103 SE-164 22 KISTA Sweden		medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing *MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
ICIM S.P.A. Piazza Don Enrico Mapelli, 75 20099 - Sesto San Giovanni (MI) Italy	0425	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion,	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		transfusion and dialysis	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices and hyperbaric chambers
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be specified)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
ITALCERT SRL Viale Sarca, 336 20126 - MILANO Italy	0426	*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except surgically devices, intended for transient use, in direct contact with central nervous system
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	Exclusion of class III medical

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0105 - Non-active ophthalmologic devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			Exclusion of medical devices utilising tissues of animal origin under Commission Regulation (EU) n. 722/2012
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
GMED SAS 1, rue Gaston Boissier 75015 PARIS France	0459	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants	EC type-examination EC verification EC declaration of conformity (full quality	Annex III Annex IV Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)			
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion			
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system EC type-examination EC verification Production quality assurance Product quality assurance	Annex II Annex III Annex IV Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam) and non-typical methods (chemical sterilisation, dry heat sterilisation, Hydrogen peroxid with or without plasma process sterilisation, Ultra High Temperature Infusion sterilisation process).
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
KIWA CERMET ITALIA S.P.A. Via Cadriano, 23 40057 - Cadriano di Granarolo (BO) Italy	0476	*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion,	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		transfusion and dialysis	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices and hyperbaric chambers for oxygen therapy
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0303 - Other medical devices for wound care	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices and devices for magnetic resonance
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation moist heat sterilisation, radiation sterilisation (gamma,xray,electron beam), dry heat
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
Eurofins Product Testing Italy S.r.l. Via Courgnè, 21 10156 - TORINO (TO) Italy	0477	*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0103 - Non-active orthopaedic and rehabilitation devices	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0100 - General non-active, non-implantable	EC type-examination	Annex III	Exclusion of class III medical

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0106 - Non-active instruments	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as utlising tissues of animal origin, including Commission Regulation (EU) N. 722/2012.
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising tissues of animal origin, including Commission Regulation (EU) N. 722/2012.
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Exclusion of class III medical

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality	Annex II Annex V	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Exclusion of class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising tissues of animal origin, including Commission Regulation (EU) N. 722/2012.
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising tissues of animal origin, including Commission Regulation (EU) N. 722/2012.
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including moist heat sterilization, aseptic processing, radiation sterilization,ethylene oxide gas sterilization (EOG)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE	0482	*MD 0300 - Devices for wound care	EC type-examination	Annex III	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
MEDIZIN GMBH Pilatuspool 2 20355 HAMBURG Germany		- *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion			
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments	quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			for active medical devices only
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
MDC MEDICAL DEVICE CERTIFICATION GMBH Kriegerstrasse 6 70191 STUTTGART Germany	0483	*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care	Full quality assurance	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0303 - Other medical devices for wound care	system Production quality assurance Product quality assurance	Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation	Full quality assurance system Production quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		(IVF) and assisted reproductive technologies (ART)	assurance Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance Product quality assurance		
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1111 - Software	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	except hyperbaric chambers
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	except external pacemakers and heart defibrillators
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Production quality assurance Product quality assurance	Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), low temperature steam and formaldehyde sterilisation, sterilisation with hydrogen peroxide, thermic sterilisation with

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					dry heat
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstädter Strasse 20 09232 Hartmannsdorf Germany	0494	*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification	Annex III Annex IV	excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification	Annex III Annex IV	excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC type-examination EC verification	Annex III Annex IV	excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Eurofins Electric & Electronics Finland Oy PL 47 Kivimiehentie 4 FI-02150 Espoo. Finland	0537	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding contact lenses, intraocular lenses and class III devices.

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1105 - Active ophthalmologic devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding active devices for sterilization and class III devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active	EC declaration of conformity (full quality	Annex II Annex V	Excluding active prosthesis and class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		prostheses	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Excluding class III
		*MDS 7006 - Medical devices in sterile condition			Limited to the following methods: aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					sterilisation, dry heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam).
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Excluding class III
CERTIQUALITY S.r.l. Via G. Giardino, 4 20123 - MILANO Italy	0546	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices, except those classified in class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding hyperbaric chambers and all devices depending on a source of electrical energy. Exclusion of class III medical devices, except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding medical devices depending on a source of electrical energy. Exclusion of class III medical devices, except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	Exclusion of class III medical

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0110 - Non-active medical devices for ingestion	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	devices, except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SGS FIMKO OY Takomotie 8 00380 HELSINKI Finland	0598	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia,	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		emergency and intensive care	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only; III, IV: Hyperbaric chambers only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only; III, IV: Nerve and muscle stimulator only
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	Up to class IIb only; III, IV: Dental units and dental patient chairs only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only; III, IV: Neurological and muscular rehabilitation devices only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only; III, IV: X-ray devices only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only; III, IV: Magnetic resonance imaging (MRI) devices only
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification	Annex III Annex IV	Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex III Annex IV Annex II Annex V Annex VI	Up to class IIb only; III, IV: Surgical ultrasoud devices only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0300 - Devices for wound care	EC declaration of	Annex II	Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0301 - Bandages and wound dressings	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Up to class IIb only
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	Up to class IIb only

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Up to class IIb only
		*MDS 7006 - Medical devices in sterile condition			Up to class IIb only
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Up to class IIb only
Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH Dovestraße 6 10587 Berlin Germany	0633	*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1107 - Active devices for disinfection and sterilisation - *MD 1112 - Medical gas supply systems and parts thereof *MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0106 - Non-active instruments *MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters - *MD 1301 - Monitoring devices of non-vital physiological parameters			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma)
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.- EKAPTY Smyrnis 15	0653	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing	EC declaration of conformity (full quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
165 62 GLYFADA Greece		radiation	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1107 - Active devices for disinfection and sterilisation	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Only for physiotherapy
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts	EC declaration of conformity (full quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		thereof	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (product quality assurance)	Annex II Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (product quality assurance)	Annex II Annex VI	Respiratory devices only
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Only for physiotherapy

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			Only for MD Codes referred above
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Only for MD Codes referred above
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, dry heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam) - Only for MD Codes referred above
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Only for MD Codes referred above
Eurofins Product Service GmbH Storkower Straße 38c 15526 REICHENWALDE Germany	0681	*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	excluding class III devices (valid for the complete scope)
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
THERAPEUTIC GOODS ADMINISTRATION 136 Narrabundah Lane Symonston ACT Australia	0805	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation,	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelel#ségértékel# és Tanúsító Korlátolt Felel#sség# Társaság (NEOEMKI LLC) Albert Flórián út 3. A. ép H-1097 Budapest Hungary	1011	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1403 - Devices for hyperthermia / hypothermia	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0103 - Non-active orthopaedic and rehabilitation devices	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Annex III. designation excluding materials of desinfecting, cleaning and rinsing . For Annex II., V., VI.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		disinfecting, cleaning, rinsing	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		there are no limitations.
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance system) EC declaration of conformity (production quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			Designation excludes products related 2003/32/EC BSE/TSE field. Designation includes Annex 2 and 5.
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV, s.p. Pod Lisem 129 171 02 PRAHA 71 - Troja Czech Republic	1014	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion,	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation,	Full quality assurance system	Annex II Annex III	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy	EC type-examination EC verification Production quality assurance Product quality assurance	Annex IV Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be specified)

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s. (INSTITUTE FOR TESTING AND CERTIFICATION) merged with ex-NB 1390 trida Tomase Bati 299 Louky, 76302 ZLIN Czech Republic	1023	*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices and contraceptive medical devices of any risk classes
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding breast implants and non-absorbable injection implants

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1104 - Active surgical devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC declaration of conformity (full quality	Annex II Annex V	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7006 - Medical devices in sterile condition			Limited to devices sterilised by one of the following: Aseptic filling, Ethylene oxide sterilisation,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					Radiation sterilisation, Moist and dry heat sterilisation
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			Limited to devices being wholly or mainly absorbed
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Excluding class III medical devices
ENTE CERTIFICAZIONE MACCHINE SRL Via Ca' Bella, 243/A - loc. Castello di Serravalle 40053 Valsamoggia (BO) Italy	1282	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ Mašera - Spasi#eva ulica 10 1000 LJUBLJANA Slovenia	1304	*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Annex III and IV for lasers only
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Only infant incubators included
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Only respiratory devices included

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	Annex III and IV for lasers only

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices	EC type-examination	Annex III	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1301 - Monitoring devices of non-vital physiological parameters	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Included only devices for injection, infusion and transfusion
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with	Full quality assurance system Production quality	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		measuring function	assurance Product quality assurance	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Excluding formaldehyde sterilisation
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
BUREAU VERITAS ITALIA S.P.A. Viale Monza, 347 20126 - MILANO (MI) Italy	1370	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Exclusion of class III medical devices - excluding hyperbaric chambers for oxygen therapy

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1200 - Devices for imaging	EC declaration of	Annex II	Exclusion of class III medical

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1201 - Imaging devices utilising ionizing radiation	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy	EC declaration of conformity (full quality	Annex II Annex V	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1403 - Devices for hyperthermia / hypothermia	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system)	Annex II Annex V Annex VI	Exclusion of class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Exclusion of class III medical devices
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including ethylene oxide gas sterilization (EOG), moist heat sterilization, radiation sterilization (gamma, x-ray, electron beam), low temperature steam.
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. ul. Pu#awska 469 02-844 Warszawa Poland	1434	*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including	EC type-examination EC verification EC declaration of conformity (full quality	Annex III Annex IV Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy	assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia *MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials - *MD 0403 - Dental implants - *MD 0401 - Non-active dental equipment and instruments			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
SGS Belgium NV Noorderlaan 87 BE-2030 Antwerpen	1639	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
Belgium		radiation	assurance system) EC declaration of conformity (production quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments	assurance system) EC declaration of conformity (production quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Excluding heartvalves

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Excluding breast implants
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and	EC declaration of conformity (full quality	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation	assurance system) EC declaration of conformity (production quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance)		
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TURKISH STANDARDS INSTITUTION (TSE)	1783	*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
Necatibey Cad. No. 112, 06100 Bakanliklar Ankara Turkey		medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0104 - Non-active medical devices with measuring function - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1111 - Software			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7006 - Medical devices in sterile condition			Only, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation and dry heat sterilisation.
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Kiwa Dare B.V. Vijzelmolenlaan 7 NL-3447 GX Woerden Netherlands	1912	*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to devices for administration and removal of substances Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices inhalation anaesthesia, lung ventilators and heart-lung machines are excluded

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of	Annex III Annex IV Annex II	Limited to non sterile class Im, IIa and IIb devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MD 1100 - General active medical devices	EC declaration of	Annex II	Limited to non sterile class Im, IIa

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1111 - Software	conformity (full quality assurance system)		and IIb devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V	Limited to non sterile class Im, IIa and IIb devices
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			Limited to non sterile class Im, IIa and IIb devices
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			Limited to non sterile class Im, IIa and IIb devices
TUV Rheinland Italia SRL Via Mattei, 3 20010 - Pogliano Milanese (MI) Italy	1936	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			assurance)		
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices and hyperbaric chambers for oxygen therapy
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices	EC type-examination	Annex III	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1104 - Active surgical devices	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex IV Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1105 - Active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (product quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC verification EC declaration of conformity (full quality assurance system) EC declaration of	Annex IV Annex II Annex V Annex VI	Excluding class III medical devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	Excluding class III medical devices
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam sterilisation, moist heat

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Kiwa Belgelendirme Hizmetleri A.#. #TOSB 9. CAD. NO:15 Tepeören Tuzla / #STANBUL Istanbul Turkey	1984	*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia,	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0106 - Non-active instruments - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0110 - Non-active medical devices for ingestion - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1108 - Active rehabilitation devices and active prostheses			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Szutest Uygunluk De#erlendirme A.#. Tatl#su Mahallesi Akif #nan Sk. No:1/1 Ümraniye / #stanbul #STANBUL Turkey	2195	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants			
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1111 - Software			
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
3EC International a.s. 3EC International a.s. Hranicna 18 Bratislava 82105 SLOVAKIA Bratislava 82105 Slovakia	2265	*MD 0100 - General non-active, non-implantable medical devices - *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			excluding Regulation 722/2012
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
TUV NORD Polska Sp. z o.o ul. Mickiewicza 29 40-085 Katowice Poland	2274	*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	Full quality assurance system Production quality assurance	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			Product quality assurance		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0100 - General non-active, non-implantable	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 0300 - Devices for wound care	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0303 - Other medical devices for wound care	conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system)	Annex II	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system)	Annex II	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system)	Annex II	
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation,	Full quality assurance system	Annex II Annex V	.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		infusion and haemopheresis	Production quality assurance Product quality assurance	Annex VI	
		*MD 1100 - General active medical devices - *MD 1103 - Devices for stimulation or inhibition	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			conformity (production quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and sterilisation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
		*MD 1100 - General active medical devices - *MD 1108 - Active rehabilitation devices and active prostheses	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V Annex VI	without acitive prostheses

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance) EC declaration of conformity (product quality assurance)		
		*MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.#. Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA Ankara Turkey	2292	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof - *MD 1103 - Devices for stimulation or inhibition *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy) *MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
					(EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft. Erd# u.101. Budakeszi Hungary	2409	*MD 1200 - Devices for imaging - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation *MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1107 - Active devices for disinfection and			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1111 - Software - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			regarding Annex II, V, VI
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			regarding Annex II, V, VI
		*MDS 7006 - Medical devices in sterile condition			regarding Annex II, V, VI Including aseptic processing, ethylene oxide gas sterilisation (EOG), radiation sterilization (gamma,x-ray, electron beam), moist heat sterilization
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			regarding Annex II, V, VI
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			regarding Annex II, V, VI

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
DNV Product Assurance AS Veritasveien 3 1363 Høvik Norway	2460	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants *MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC,			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others.
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
Notice Belgelendirme, Muayene ve Denetim Hizmetleri Anonim #irketi Esentepe Mahallesi Milangaz Caddesi No:75 A/92 Kartal/#stanbul Istanbul Turkey	2764	*MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0403 - Dental implants	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Only infusion devices
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	excluding hyperbaric chambers for oxygen therapy
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance)		
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1402 - Devices utilising non-ionizing radiation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion,	EC declaration of conformity (full quality assurance system)	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		transfusion and dialysis	EC declaration of conformity (production quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants	EC declaration of	Annex II	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0203 - Non-active functional implants	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 0200 - Non-active implants - *MD 0204 - Non-active soft tissue implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Only felts and similar technologies
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care - *MD 0303 - Other medical devices for wound care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance)		
		*MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic, processing, ethylene oxide gas, sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands	2797	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis - *MD 0103 - Non-active orthopaedic and rehabilitation	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of	Annex II Annex V Annex VI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		devices - *MD 0104 - Non-active medical devices with measuring function - *MD 0105 - Non-active ophthalmologic devices - *MD 0106 - Non-active instruments - *MD 0107 - Contraceptive medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing - *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) - *MD 0110 - Non-active medical devices for ingestion *MD 0200 - Non-active implants - *MD 0201 - Non-active cardiovascular implants - *MD 0202 - Non-active orthopaedic implants - *MD 0203 - Non-active functional implants - *MD 0204 - Non-active soft tissue implants *MD 0300 - Devices for wound care - *MD 0301 - Bandages and wound dressings - *MD 0302 - Suture material and clamps - *MD 0303 - Other medical devices for wound care *MD 0400 - Non-active dental devices and accessories - *MD 0401 - Non-active dental equipment and instruments - *MD 0402 - Dental materials - *MD 0403 - Dental implants *MD 1100 - General active medical devices	conformity (product quality assurance)		

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia - *MD 1103 - Devices for stimulation or inhibition - *MD 1104 - Active surgical devices - *MD 1105 - Active ophthalmologic devices - *MD 1106 - Active dental devices - *MD 1107 - Active devices for disinfection and sterilisation - *MD 1108 - Active rehabilitation devices and active prostheses - *MD 1109 - Active devices for patient positioning and transport - *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART) - *MD 1111 - Software - *MD 1112 - Medical gas supply systems and parts thereof *MD 1200 - Devices for imaging - *MD 1201 - Imaging devices utilising ionizing radiation - *MD 1202 - Imaging devices utilising non-ionizing radiation *MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		physiological parameters - *MD 1302 - Monitoring devices of vital physiological parameters *MD 1400 - Devices for radiation therapy and thermo therapy - *MD 1401 - Devices utilising ionizing radiation - *MD 1402 - Devices utilising non-ionizing radiation - *MD 1403 - Devices for hyperthermia / hypothermia - *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)			
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)			
		*MDS 7003 - Medical devices incorporating derivates of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC			
		*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery			
		*MDS 7006 - Medical devices in sterile condition			
		*MDS 7007 - Medical devices utilising micromechanics			
		*MDS 7008 - Medical devices utilising nanomaterials			
		*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed			
		*MDS 7010 - Medical devices incorporating software			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		/utilising software /controlled by software			
G.F.I. Health Technology Certification Ltd Jacovides Tower 81-83 Grivas Digenis Avenue 1090 Nicosia Cyprus	2803	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0103 - Non-active orthopaedic and rehabilitation devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system)	Annex II Annex V	Except Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Male Condoms only
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 0200 - Non-active implants - *MD 0202 - Non-active orthopaedic implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0300 - Devices for wound care	EC declaration of	Annex II	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		- *MD 0301 - Bandages and wound dressings	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	
		*MD 0300 - Devices for wound care - *MD 0302 - Suture material and clamps	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V	Respiratory Devices only, Except Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance)		
		*MD 1100 - General active medical devices - *MD 1104 - Active surgical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1111 - Software	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 1100 - General active medical devices - *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Except Class III Medical Devices
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system)	Annex II Annex V	Except Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC			
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilization (EOG), moist heat sterilization, radiation sterilization
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			
bqs. s.r.o. Študentská 1641/12 Tren#ín, 911 01 Slovakia	2854	*MD 0100 - General non-active, non-implantable medical devices - *MD 0101 - Non-active devices for anaesthesia, emergency and intensive care	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class I sterile, class I with measuring function, class IIa and class IIb
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class I sterile, class I with measuring function, class IIa and class IIb
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0104 - Non-active medical devices with measuring function	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production	Annex II Annex V	Medical devices of class I sterile, class I with measuring function, class IIa and class IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			quality assurance)		
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0105 - Non-active ophthalmologic devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class I sterile, class I with measuring function, class IIa and class IIb
		*MD 0100 - General non-active, non-implantable medical devices - *MD 0106 - Non-active instruments	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class I sterile, class I with measuring function, class IIa and class IIb
		*MD 0400 - Non-active dental devices and accessories - *MD 0402 - Dental materials	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class I sterile, class IIa and class IIb
		*MD 0400 - Non-active dental devices and accessories - *MD 0403 - Dental implants	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class IIa and class IIb
		*MD 1100 - General active medical devices - *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system)	Annex II Annex V	Medical devices of class IIa and class IIb

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 93/42/EEC Medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
			EC declaration of conformity (production quality assurance)		
		*MD 1100 - General active medical devices - *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class IIa and class IIb excluding hyperbaric chambers
		*MD 1100 - General active medical devices - *MD 1106 - Active dental devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class IIa and class IIb
		*MD 1300 - Monitoring devices - *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class I sterile, class I with measuring function, class IIa and class IIb
		*MD 1300 - Monitoring devices - *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Medical devices of class IIa and class IIb
		*MD 1400 - Devices for radiation therapy and thermo	EC declaration of	Annex II	Medical devices of class IIa and

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Limitations (English only)
		therapy - *MD 1402 - Devices utilising non-ionizing radiation	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V	class IIb
		*MDS 7006 - Medical devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others
		*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software			