

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
National Standards Authority of Ireland (NSAI) 1 Swift Square, Northwood, Santry Dublin 9 Ireland	0050	*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0301 - Anti-Duffy and anti-Kidd - *IVD 0302 - Irregular anti-erythrocytic antibodies - *IVD 0303 - Congenital infections: rubella, toxoplasmosis - *IVD 0304 - Hereditary disease: phenylketonuria - *IVD 0305 - Human infections: cytomegalovirus, chlamydia - *IVD 0306 - HLA tissue groups: DR, A, B - *IVD 0307 - Tumoral marker: PSA - *IVD 0308 - Risk of trisomy 21 (incl. software) - *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar *IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology - *IVD 0404 - Molecular biology - *IVD 0405 - Pregnancy and ovulation - *IVD 0406 - Specimen receptacles *MDS 7205 - IVDs incorporating software / utilising software / controlled by software *MDS 7206 - IVDs in sterile condition	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	

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BSI Assurance UK Ltd Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom	0086	<p>*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups</p> <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> <p>*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of</p> <ul style="list-style-type: none"> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> <li>- *IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD)</li> </ul> <p>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</p> <ul style="list-style-type: none"> <li>- *IVD 0301 - Anti-Duffy and anti-Kidd</li> <li>- *IVD 0302 - Irregular anti-erythrocytic antibodies</li> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0306 - HLA tissue groups: DR, A, B</li> </ul>	EC declaration of conformity  EC verification  EC declaration of conformity (full quality assurance system)	Annex III  Annex VI  Annex IV	

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		<ul style="list-style-type: none"> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0402 - Haematology</li> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> <li>- *IVD 0404 - Molecular biology</li> </ul>			
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs 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 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
SGS United Kingdom Limited	0120	*IVD 0300 - Reagents, reagent products and devices for	Full quality assurance	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)
Unit 202B, Worle Parkway, Weston-super-Mare, Somerset, BS22 6WA United Kingdom		self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0301 - Anti-Duffy and anti-Kidd	system Production quality assurance	Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0302 - Irregular anti-erythrocytic antibodies	Full quality assurance system Production quality assurance	Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0303 - Congenital infections: rubella, toxoplasmosis	Full quality assurance system Production quality assurance	Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0304 - Hereditary disease: phenylketonuria	Full quality assurance system Production quality assurance	Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0305 - Human infections: cytomegalovirus, chlamydia	Full quality assurance system Production quality assurance	Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control	Full quality assurance system	Annex IV Annex VII	

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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)
		materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0306 - HLA tissue groups: DR, A, B	Production quality assurance		
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0307 - Tumoral marker: PSA	Full quality assurance system Production quality assurance	Annex IV Annex VII	Restricted to PSA controls
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0308 - Risk of trisomy 21 (incl. software)	Full quality assurance system Production quality assurance	Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	Full quality assurance system Production quality assurance	Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0402 - Haematology	EC declaration of conformity Full quality assurance	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)
			system Production quality assurance	Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0403 - Immunology	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0406 - Specimen receptacles	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0404 - Molecular biology	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of	Annex III Annex IV Annex VII	

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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)		
		*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0101 - ABO system	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
		*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
		*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0103 - Anti-Kell	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0201 - HIV infection (HIV 1 and 2)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the	EC declaration of conformity (full quality	Annex IV Annex VII	

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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)
		detection, confirmation and quantification in human specimens of markers of - *IVD 0202 - HTLV I and II	assurance system) EC declaration of conformity (production quality assurance)		
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0203 - Hepatitis B, C and D	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs in sterile condition			EC declaration of conformity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII
		*MDS 7209 - IVDs utilising biological active coating and/or material			EC declaration of conformity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII
		*MDS 7210 - IVDs utilising material of human origin			EC declaration of conformity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII
TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65 80339 MÜNCHEN Germany	0123	*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0102 - Rhesus (C, c, D, E, e)	Full quality assurance system EC type-examination Production quality	Annex IV Annex V Annex VII	



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		<ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> *IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of <ul style="list-style-type: none"> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> </ul>	assurance		
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of <ul style="list-style-type: none"> <li>- *IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD)</li> </ul>	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating <ul style="list-style-type: none"> <li>- *IVD 0301 - Anti-Duffy and anti-Kidd</li> <li>- *IVD 0302 - Irregular anti-erythrocytic antibodies</li> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> </ul>	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification,	Full quality assurance system Production quality	Annex IV Annex VII	

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		diagnosing, evaluating - *IVD 0304 - Hereditary disease: phenylketonuria	assurance		
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0305 - Human infections: cytomegalovirus, chlamydia - *IVD 0306 - HLA tissue groups: DR, A, B - *IVD 0307 - Tumoral marker: PSA	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0308 - Risk of trisomy 21 (incl. software)	Full quality assurance system Production quality assurance	Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology - *IVD 0404 - Molecular biology - *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity Full quality assurance system EC type-examination EC verification	Annex III Annex IV Annex V Annex VI Annex VII	

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		- *IVD 0406 - Specimen receptacles	Production quality assurance		
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs 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, sterilisation with liquid sterilants
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany	0197	*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0101 - ABO system - *IVD 0102 - Rhesus (C, c, D, E, e) - *IVD 0103 - Anti-Kell  *IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the	Full quality assurance system EC type-examination  Production quality assurance	Annex IV Annex V Annex VII	

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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)
		detection, confirmation and quantification in human specimens of markers of - *IVD 0201 - HIV infection (HIV 1 and 2) - *IVD 0202 - HTLV I and II - *IVD 0203 - Hepatitis B, C and D			
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0301 - Anti-Duffy and anti-Kidd - *IVD 0302 - Irregular anti-erythrocytic antibodies - *IVD 0303 - Congenital infections: rubella, toxoplasmosis - *IVD 0304 - Hereditary disease: phenylketonuria - *IVD 0305 - Human infections: cytomegalovirus, chlamydia - *IVD 0306 - HLA tissue groups: DR, A, B - *IVD 0307 - Tumoral marker: PSA - *IVD 0308 - Risk of trisomy 21 (incl. software) - *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology - *IVD 0404 - Molecular biology	EC declaration of conformity Full quality assurance system EC type-examination EC verification	Annex III Annex IV Annex V Annex VI Annex VII	

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		<ul style="list-style-type: none"> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	Production quality assurance		
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs 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 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS Campezo 1. Edificio 8 28022 MADRID Spain	0318	*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> *IVD 0200 - Reagents and reagent products, including	EC type-examination  EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)	Annex V  Annex IV  Annex VII	

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		related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0201 - HIV infection (HIV 1 and 2) - *IVD 0202 - HTLV I and II - *IVD 0203 - Hepatitis B, C and D			
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0301 - Anti-Duffy and anti-Kidd - *IVD 0302 - Irregular anti-erythrocytic antibodies - *IVD 0303 - Congenital infections: rubella, toxoplasmosis - *IVD 0304 - Hereditary disease: phenylketonuria - *IVD 0305 - Human infections: cytomegalovirus, chlamydia - *IVD 0306 - HLA tissue groups: DR, A, B - *IVD 0307 - Tumoral marker: PSA - *IVD 0308 - Risk of trisomy 21 (incl. software) - *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex VI Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology	EC declaration of conformity EC type-examination EC verification EC declaration of	Annex III Annex V Annex VI Annex IV	

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		<ul style="list-style-type: none"> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VII	
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
DEKRA Certification B.V. Meander 1051 / P.O. Box 5185 6825 MJ ARNHEM / 6802 ED ARNHEM Netherlands	0344	*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> *IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of <ul style="list-style-type: none"> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> </ul> *IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification,	EC declaration of conformity Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	

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		diagnosing, evaluating - *IVD 0303 - Congenital infections: rubella, toxoplasmosis - *IVD 0304 - Hereditary disease: phenylketonuria - *IVD 0305 - Human infections: cytomegalovirus, chlamydia - *IVD 0306 - HLA tissue groups: DR, A, B - *IVD 0307 - Tumoral marker: PSA - *IVD 0308 - Risk of trisomy 21 (incl. software) - *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar - *IVD 0301 - Anti-Duffy and anti-Kidd - *IVD 0302 - Irregular anti-erythrocytic antibodies *IVD 0400 - Devices for self-testing - *IVD 0402 - Haematology - *IVD 0403 - Immunology - *IVD 0404 - Molecular biology - *IVD 0405 - Pregnancy and ovulation - *IVD 0406 - Specimen receptacles - *IVD 0401 - Clinical chemistry			
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating			



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		and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
ISTITUTO SUPERIORE DI SANITA' Viale Regina Elena, 299 00161 - ROMA Italy	0373	*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of  - *IVD 0201 - HIV infection (HIV 1 and 2) - *IVD 0202 - HTLV I and II	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V Annex VII	
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of  - *IVD 0203 - Hepatitis B, C and D	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating  - *IVD 0303 - Congenital infections: rubella, toxoplasmosis - *IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex VI Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing  - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology	EC declaration of conformity	Annex III	

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		<ul style="list-style-type: none"> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>			
GMED 1, rue Gaston Boissier 75015 PARIS France	0459	*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating <ul style="list-style-type: none"> <li>- *IVD 0307 - Tumoral marker: PSA</li> </ul>	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex VI Annex IV Annex VII	
		*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> *IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of <ul style="list-style-type: none"> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> </ul> *IVD 0400 - Devices for self-testing <ul style="list-style-type: none"> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0402 - Haematology</li> </ul>	EC declaration of conformity Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> <li>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> <li>- *IVD 0301 - Anti-Duffy and anti-Kidd</li> <li>- *IVD 0302 - Irregular anti-erythrocytic antibodies</li> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0306 - HLA tissue groups: DR, A, B</li> </ul>			
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
MDC MEDICAL DEVICE CERTIFICATION GMBH Kriegerstrasse 6 70191 STUTTGART Germany	0483	*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0101 - ABO system - *IVD 0102 - Rhesus (C, c, D, E, e) - *IVD 0103 - Anti-Kell  *IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0201 - HIV infection (HIV 1 and 2) - *IVD 0203 - Hepatitis B, C and D	Full quality assurance system  Production quality assurance	Annex IV  Annex VII	
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD) - *IVD 0202 - HTLV I and II	EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)	Annex IV  Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0301 - Anti-Duffy and anti-Kidd - *IVD 0302 - Irregular anti-erythrocytic antibodies - *IVD 0303 - Congenital infections: rubella, toxoplasmosis	Full quality assurance system  Production quality assurance	Annex IV  Annex VII	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0306 - HLA tissue groups: DR, A, B</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> </ul>			
		<ul style="list-style-type: none"> <li>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</li> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> </ul>	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
		<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0402 - Haematology</li> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
		<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0404 - Molecular biology</li> </ul>	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs 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, thermic sterilisation with dry heat
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
Eurofins Expert Services Oy PL 47 Kivimiehentie 4 FI-02150 Espoo. Finland	0537	*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of  - *IVD 0201 - HIV infection (HIV 1 and 2) - *IVD 0202 - HTLV I and II - *IVD 0203 - Hepatitis B, C and D	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	Annex III  Annex IV	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating  - *IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity (full quality assurance system)	Annex IV	

## LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> </ul>			
		<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	Annex III Annex IV	
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, dry heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		*MDS 7210 - IVDs utilising material of human origin			
Presafe Denmark A/S Tuborg Parkvej 8 DK-2900 Hellerup Denmark	0543	<ul style="list-style-type: none"> <li>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</li> <li>- *IVD 0303 - Congenital infections: rubella,</li> </ul>	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex V Annex VI Annex IV Annex VII	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		toxoplasmosis - *IVD 0305 - Human infections: cytomegalovirus, chlamydia - *IVD 0307 - Tumoral marker: PSA	EC declaration of conformity (production quality assurance)		
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0301 - Anti-Duffy and anti-Kidd - *IVD 0302 - Irregular anti-erythrocytic antibodies *IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0101 - ABO system - *IVD 0102 - Rhesus (C, c, D, E, e) - *IVD 0103 - Anti-Kell *IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0201 - HIV infection (HIV 1 and 2) - *IVD 0202 - HTLV I and II - *IVD 0203 - Hepatitis B, C and D	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology	EC declaration of conformity EC type-examination EC verification	Annex III Annex V Annex VI Annex IV	



**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VII	
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7210 - IVDs utilising material of human origin			
UL INTERNATIONAL (UK) LTD Womersley House Building C The Guildway Old Portsmouth Road Guildford GU3 1LR United Kingdom	0843	*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating  - *IVD 0308 - Risk of trisomy 21 (incl. software)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
NEOEMKI Nemzeti Orvostechikai Eszköz Megfelel#ségértékel# és Tanúsító Korlátolt Felel#sség# Társaság (NEOEMKI LLC) Albert Flórián út 3. A. ép H-1097 Budapest Hungary	1011	*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> *IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating  - *IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity (full quality assurance system)	Annex IV	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> </ul>			
		<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0402 - Haematology</li> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	EC declaration of conformity  EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs 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 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s. T. Bati 299 Louky, 76302 ZLIN Czech Republic	1023	<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0402 - Haematology</li> </ul>	EC declaration of conformity  Full quality assurance system	Annex III Annex IV Annex V	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	EC type-examination EC verification Production quality assurance	Annex VI Annex VII	
		*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> *IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of <ul style="list-style-type: none"> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> </ul>	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating <ul style="list-style-type: none"> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the</li> </ul>	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		measurement of blood sugar - *IVD 0301 - Anti-Duffy and anti-Kidd - *IVD 0302 - Irregular anti-erythrocytic antibodies - *IVD 0305 - Human infections: cytomegalovirus, chlamydia - *IVD 0306 - HLA tissue groups: DR, A, B			
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
EVPU a.s. Trencianska 19 018 51 NOVA DUBNICA Slovakia	1293	*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0101 - ABO system	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups - *IVD 0103 - Anti-Kell	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human	EC declaration of conformity (full quality assurance system)	Annex IV	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		specimens of markers of - *IVD 0201 - HIV infection (HIV 1 and 2)			
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0202 - HTLV I and II	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0203 - Hepatitis B, C and D	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of - *IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD)	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating	EC declaration of conformity (full quality assurance system)	Annex IV	

## LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		- *IVD 0305 - Human infections: cytomegalovirus, chlamydia			
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0306 - HLA tissue groups: DR, A, B	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating - *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity (full quality assurance system)	Annex IV	
		*IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry	EC declaration of conformity EC declaration of conformity (full quality assurance system)	Annex III Annex IV	Annex III - point 6.
		*IVD 0400 - Devices for self-testing - *IVD 0402 - Haematology	EC declaration of conformity EC declaration of conformity (full quality assurance system)	Annex III Annex IV	Annex III - point 6.
		*IVD 0400 - Devices for self-testing - *IVD 0403 - Immunology	EC declaration of conformity EC declaration of conformity (full quality assurance system)	Annex III Annex IV	Annex III - point 6.

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		*IVD 0400 - Devices for self-testing - *IVD 0404 - Molecular biology	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	Annex III Annex IV	Annex III - point 6.
		*IVD 0400 - Devices for self-testing - *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	Annex III Annex IV	Annex III - point 6.
		*IVD 0400 - Devices for self-testing - *IVD 0406 - Specimen receptacles	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	Annex III Annex IV	Annex III - point 6.
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs 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 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.	1434	*IVD 0100 - Reagents and reagent products, including	EC declaration of	Annex III	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
ul. Klobucka 23A 02-699 Warszawa Poland		<p>related calibrators and control materials, for determining the following blood groups</p> <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> <p>*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of</p> <ul style="list-style-type: none"> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> </ul> <p>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</p> <ul style="list-style-type: none"> <li>- *IVD 0302 - Irregular anti-erythrocytic antibodies</li> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0306 - HLA tissue groups: DR, A, B</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> <li>- *IVD 0301 - Anti-Duffy and anti-Kidd</li> </ul>	<p>conformity</p> <p>EC type-examination</p> <p>EC verification</p> <p>EC declaration of conformity (full quality assurance system)</p> <p>EC declaration of conformity (production quality assurance)</p>	<p>Annex V</p> <p>Annex VI</p> <p>Annex IV</p> <p>Annex VII</p>	



**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		- *IVD 0308 - Risk of trisomy 21 (incl. software) *IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology - *IVD 0404 - Molecular biology - *IVD 0405 - Pregnancy and ovulation - *IVD 0406 - Specimen receptacles			
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
TURKISH STANDARDS INSTITUTION (TSE) Necatibey Cad. No. 112, 06100 Bakanliklar Ankara Turkey	1783	*IVD 0400 - Devices for self-testing - *IVD 0401 - Clinical chemistry - *IVD 0402 - Haematology - *IVD 0403 - Immunology - *IVD 0404 - Molecular biology - *IVD 0405 - Pregnancy and ovulation - *IVD 0406 - Specimen receptacles	EC declaration of conformity  EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
		*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating	EC declaration of conformity (full quality assurance system)	Annex IV Annex VII	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> <li>- *IVD 0301 - Anti-Duffy and anti-Kidd</li> <li>- *IVD 0302 - Irregular anti-erythrocytic antibodies</li> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0306 - HLA tissue groups: DR, A, B</li> </ul>	EC declaration of conformity (production quality assurance)		
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
3EC International a.s. 3EC International a.s. Hranicna 18 Bratislava 82105 SLOVAKIA Bratislava 82105 Slovakia	2265	*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating <ul style="list-style-type: none"> <li>- *IVD 0301 - Anti-Duffy and anti-Kidd</li> <li>- *IVD 0302 - Irregular anti-erythrocytic antibodies</li> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> </ul>	EC declaration of conformity (full quality assurance system)	Annex IV	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0306 - HLA tissue groups: DR, A, B</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> </ul>			
		<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0402 - Haematology</li> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	Annex III Annex IV	
		<ul style="list-style-type: none"> <li>*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups               <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> </li> <li>*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of               <ul style="list-style-type: none"> <li>- *IVD 0202 - HTLV I and II</li> </ul> </li> </ul>	EC declaration of conformity (full quality assurance system)	Annex IV	

**LIST OF BODIES NOTIFIED UNDER DIRECTIVE : 98/79/EC In vitro diagnostic 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)
		<ul style="list-style-type: none"> <li>- *IVD 0203 - Hepatitis B, C and D</li> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> </ul>			
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft. Erd# u.101. Budakeszi Hungary	2409	*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating  <ul style="list-style-type: none"> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> </ul>	EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
		*IVD 0400 - Devices for self-testing <ul style="list-style-type: none"> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> <li>- *IVD 0401 - Clinical chemistry</li> </ul>	EC declaration of conformity  EC declaration of conformity (full quality assurance system)  EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			regarding Annex II, IV, VII

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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 7206 - IVDs in sterile condition			regarding Annex II, IV, VII
		*MDS 7209 - IVDs utilising biological active coating and/or material			regarding Annex II, IV, VII
BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands	2797	<p>*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups</p> <ul style="list-style-type: none"> <li>- *IVD 0101 - ABO system</li> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> </ul> <p>*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of</p> <ul style="list-style-type: none"> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> <li>- *IVD 0204 - Variant Creutzfeldt-Jakob disease (vCJD)</li> </ul> <p>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</p> <ul style="list-style-type: none"> <li>- *IVD 0301 - Anti-Duffy and anti-Kidd</li> <li>- *IVD 0302 - Irregular anti-erythrocytic antibodies</li> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> <li>- *IVD 0304 - Hereditary disease: phenylketonuria</li> </ul>	EC declaration of conformity (full quality assurance system)	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)
		<ul style="list-style-type: none"> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0306 - HLA tissue groups: DR, A, B</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0308 - Risk of trisomy 21 (incl. software)</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> </ul>			
		<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing</li> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0402 - Haematology</li> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul>	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	Annex III Annex IV	
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs in sterile condition			
		*MDS 7207 - IVDs utilising micromechanics			
		*MDS 7208 - IVDs utilising nanomaterials			
		*MDS 7209 - IVDs utilising biological active coating and/or material			
		*MDS 7210 - IVDs utilising material of human origin			
bqs. s.r.o. Študentská 1641/12 Trenčín, 911 01 Slovakia	2854	<ul style="list-style-type: none"> <li>*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups</li> <li>- *IVD 0101 - ABO system</li> </ul>	EC declaration of conformity (full quality assurance system)	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)
		<ul style="list-style-type: none"> <li>- *IVD 0102 - Rhesus (C, c, D, E, e)</li> <li>- *IVD 0103 - Anti-Kell</li> <li>*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of               <ul style="list-style-type: none"> <li>- *IVD 0201 - HIV infection (HIV 1 and 2)</li> <li>- *IVD 0202 - HTLV I and II</li> <li>- *IVD 0203 - Hepatitis B, C and D</li> </ul> </li> <li>*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating               <ul style="list-style-type: none"> <li>- *IVD 0303 - Congenital infections: rubella, toxoplasmosis</li> <li>- *IVD 0305 - Human infections: cytomegalovirus, chlamydia</li> <li>- *IVD 0307 - Tumoral marker: PSA</li> <li>- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar</li> </ul> </li> </ul>			
		<ul style="list-style-type: none"> <li>*IVD 0400 - Devices for self-testing               <ul style="list-style-type: none"> <li>- *IVD 0401 - Clinical chemistry</li> <li>- *IVD 0402 - Haematology</li> <li>- *IVD 0403 - Immunology</li> <li>- *IVD 0404 - Molecular biology</li> <li>- *IVD 0405 - Pregnancy and ovulation</li> <li>- *IVD 0406 - Specimen receptacles</li> </ul> </li> </ul>	EC declaration of conformity  EC declaration of conformity (full quality assurance system)	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)
		*MDS 7205 - IVDs incorporating software / utilising software / controlled by software			
		*MDS 7206 - IVDs 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)