

Notification of a Body in the framework of a technical harmonization directive

From : Department of Health Medicines
and Healthcare Products
Regulatory Agency (MHRA)
151 Buckingham Palace Road,
Victoria,
London SW1W 9SZ.
United Kingdom

To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.
Other Member States

Reference :

Legislation : 90/385/EEC Active implantable medical devices

Body name, address, telephone, fax, email, website :

BSI Assurance UK Ltd
Kitemark Court Davy Avenue Knowlhill
Milton Keynes MK5 8PP
United Kingdom
Phone : +44 (0) 8450 809000
Fax : +44 (0) 8450 809000
Email : product.certification@bsigroup.com
Website : www.bsigroup.com

Body :

NB 0086

The body is formally accredited against :

EN ISO/IEC 17021 - Certification of management systems

Name of National Accreditation Body (NAB) : UKAS - United Kingdom Accreditation Service

The accreditation covers the product categories and conformity assessment procedures concerned by this notification : Yes

Tasks performed by the Body :

Last approval date : 28/01/2020

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
*AIMD 0100 - General active implantable medical devices			
- *AIMD 0101 - Active implantable medical devices for stimulation / inhibition	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality) EC type-examination	Annex 2 Annex 5 Annex 3	
- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5	
- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions	EC declaration of conformity (complete quality assurance system) EC declaration of conformity to type (assurance of production quality)	Annex 2 Annex 5	

Horizontal technical competence	Limitations
*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 derivatives 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), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), others (need to be specified)
*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	