



BSI Assurance UK Ltd
Kitemark Court
Davy Avenue
Milton Keynes
MK5 8PP

Approved Body: BSI Assurance UK Ltd 0086

Legislation: Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002).

Reference: Active Implantable Medical Devices

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

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives [as modified by Part I of Schedule 2A to the Medical Devices Regulations 2002]	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	Annex 2 Annex 5	

	type (assurance of production quality)		
Horizontal technical competence		Limitations	
*MDS 7001 - Medical devices incorporating medicinal substances according to The Human Medicines Regulations 2012			
*MDS 7002 - Medical devices utilising tissues of animal origin including Regulation 722/2012			
*MDS 7003 - Medical devices incorporating derivatives of human blood according to UK Medical Devices Regulations 2002			
*MDS 7004 - Medical devices referencing The Supply of Machinery (Safety) Regulations 2008			
*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), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agents, thermic sterilisation with dry heat, sterilisation with supercritical carbon dioxide, sterilisation with nitrogen dioxide, sterilisation with chlorine dioxide	
*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 absorbable			
*MDS 7010 - Medical devices incorporating software / utilising software / controlled by software			