



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

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	Complete quality assurance system Assurance of production quality	Annex 2 Annex 5	
AIMD 0102 - Active implantable medical devices delivering drugs or other substances	Complete quality assurance system Assurance of production quality	Annex 2 Annex 5	
AIMD 0103 - Active implantable medical devices substituting or replacing organ functions	Complete quality assurance system Assurance of production quality	Annex 2 Annex 5	

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 absorbed	
MDS 7010 - Medical devices incorporating software / utilising software / controlled by software	