



Medicines & Healthcare products  
Regulatory Agency

DEKRA Certification UK Ltd  
Stokenchurch House  
Oxford Road  
Stokenchurch  
High Wycombe  
HP14 3SX

**Approved Body:** DEKRA Certification UK Ltd (8505)

**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
<b>AIMD 0100 - General active implantable medical devices</b>			
AIMD 0101 - Active implantable medical devices for stimulation / inhibition	EC declaration of conformity (full quality assurance system)	Annex II	
AIMD 0102 - Active implantable medical devices delivering drugs or other substances	EC declaration of conformity (full quality assurance system)	Annex II	
AIMD 0103 - Active implantable medical devices substituting or replacing organ functions	EC declaration of conformity (full quality assurance system)	Annex II	

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	
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	