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United Kingdom

**Approved Body:** TUV SUD BABT Unlimited AB 0168

**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)	Annex 2	
- *AIMD 0102 - Active implantable medical devices delivering drugs or other substances	EC declaration of conformity (complete quality assurance system)	Annex 2	

- *AIMD 0103 - Active implantable medical devices substituting or replacing organ functions	EC declaration of conformity (complete quality assurance system)	Annex 2	
<b>Horizontal technical competence</b>		<b>Limitations</b>	
*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 derivates 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 7008 - Medical devices utilising nanomaterials			
*MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbd			
*MDS 7010 - Medical devices incorporating software / utilising software / controlled by software			