



LNE-GMED UK Limited
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Hertfordshire
HP2 7BW

Approved Body: LNE-GMED UK Limited

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 III 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 EC type-examination EC verification Assurance of production quality	Annex II Annex III Annex IV Annex V	
AIMD 0102 - Active implantable medical devices delivering drugs or other substances	Complete quality assurance system EC type-examination EC verification Assurance of production quality	Annex II Annex III Annex IV Annex V	

AIMD 0103 - Active implantable medical devices substituting or replacing organ functions	Complete quality assurance system EC type-examination EC verification Assurance of production quality	Annex II Annex III Annex IV Annex V	
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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 Commission Regulation (EU) No 722/20121	
MDS 7004 - Medical devices referencing The Supply of Machinery (Safety) Regulations 2008	
MDS 7006 - Medical devices in sterile condition	Including ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
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	