Medicines & Healthcare products Regulatory Agency

LNE-GMED UK Limited
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Approved Body: LNE-GMED UK Limited

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

Reference: 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 II of Schedule 2A to the Medical Devices Regulations 2002]	Limitations
MD 0100 - General non-active, non-implantable medical devices			
*MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 0104 - Non-active medical devices with measuring function	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

*MD 0105 - Non-active ophthalmologic devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 0106 - Non-active instruments	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 0108 – Non-active medical devices for disinfecting, cleaning, rinsing	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
MD 0200 - Non-active implants			
*MD 0201 - Non-active cardiovascular implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 0202 – Non-active orthopaedic implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
MD 0300 - Devices for wound care			
*MD 0301 - Bandages and wound dressings	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 0302 – Suture material and clamps	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

*MD 0303 – Other medical devices for wound care	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
MD 0400 - Non-active dental devices and accessories			
*MD 0402 - Dental materials	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 0403 - Dental implants	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
MD 1100 - General active medical devices			
*MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1103 - Devices for stimulation or inhibition	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1104 - Active surgical devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity	Annex III Annex IV Annex II Annex V Annex VI	

	(product quality assurance)		
*MD 1106 - Active dental devices	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1108 - Active rehabilitation devices and active prostheses	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1111 - Software	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1112 - Parts incorporated within Medical gas supply systems	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	Excluding medical gas pipelines (Not considered to be medical devices). Including parts of the system such as regulators and valves.x
MD 1200 - Devices for imaging			
*MD 1201 - Imaging devices utilising ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
*MD 1202 - Imaging devices utilising non-ionizing radiation	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	
MD 1300 - Monitoring devices			
*MD 1301 - Monitoring devices of non-vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system)	Annex III Annex IV Annex II	

	EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex V Annex VI	
*MD 1302 - Monitoring devices of vital physiological parameters	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex III Annex IV Annex II Annex V Annex VI	

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 722/2012	
*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	