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Approved Body: SGS United Kingdom Limited 0120

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

EN ISO/IEC 17065 - Product certification

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 0101 - Non-active devices for anaesthesia, emergency and intensive care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

- *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0110 - Non-active medical devices for ingestion	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
*MD 0200 - Non-active implants			
- *MD 0201 - Non-active cardiovascular implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	Excluding Breast Implants
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

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- *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 0400 - Non-active dental devices and accessories			
- *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0402 - Dental materials	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 0403 - Dental implants	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 1100 - General active medical devices			
- *MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1105 - Active ophthalmologic devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1111 - Software	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

- *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
*MD 1200 - Devices for imaging			
- *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	

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
	Product quality assurance	Annex VI	
- *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
*MD 1300 - Monitoring devices			
- *MD 1301 - Monitoring devices of non-vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
- *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance) EC declaration of conformity (product quality assurance)	Annex II Annex V Annex VI	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1403 - Devices for hyperthermia / hypothermia	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
- *MD 1404 - Devices for (extracorporeal) shock-wave therapy (lithotripsy)	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	

Horizontal technical competence	Limitations
*MDS 7001 - Medical devices incorporating medicinal substances, according to Directive 2001/83/EC	

*MDS 7002 - Medical devices utilising tissues of animal origin, including Regulation 722/2012 (Directive 2003/32/EC up to 28.08.2013)	
*MDS 7004 - Medical devices referencing the Directive 2006/42/EC on machinery	
*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 absorbed	
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	