Medicines & Healthcare products Regulatory Agency

SGS United Kingdom Limited
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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	Annex II Annex V	
- *MD 0102 - Non-active devices for injection, infusion, transfusion and dialysis	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
- *MD 0103 - Non-active orthopaedic and rehabilitation devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0104 - Non-active medical devices with measuring function	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0105 - Non-active ophthalmologic devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0106 - Non-active instruments	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0107 - Contraceptive medical devices	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 0108 - Non-active medical devices for disinfecting, cleaning, rinsing	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 0200 - Non-active implants			
- *MD 0201 - Non-active cardiovascular implants	Full quality assurance system	Annex II Annex V	

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	Production quality assurance		
- *MD 0202 - Non-active orthopaedic implants	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0203 - Non-active functional implants	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0204 - Non-active soft tissue implants	Full quality assurance system Production quality assurance	Annex II Annex V	Excluding Breast Implants
*MD 0300 - Devices for wound care			
- *MD 0301 - Bandages and wound dressings	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0302 - Suture material and clamps	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0303 - Other medical devices for wound care	Full quality assurance system Production quality assurance	Annex II Annex V	
*MD 0400 - Non-active dental devices and accessories			
- *MD 0401 - Non-active dental equipment and instruments	Full quality assurance system Production quality assurance	Annex II Annex V	

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- *MD 0402 - Dental materials	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 0403 - Dental implants	Full quality assurance system Production quality assurance	Annex II Annex V	
*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)	Annex II Annex V	
- *MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1103 - Devices for stimulation or inhibition	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
- *MD 1104 - Active surgical devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1105 - Active ophthalmologic devices	Full quality assurance system	Annex II Annex V	

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	Production quality assurance		
- *MD 1106 - Active dental devices	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1107 - Active devices for disinfection and sterilisation	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1108 - Active rehabilitation devices and active prostheses	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1109 - Active devices for patient positioning and transport	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1110 - Active devices for in vitro fertilisation (IVF) and assisted reproductive therapy (ART)	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1111 - Software	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1112 - Medical gas supply systems and parts thereof	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	Excluding medical gas pipelines (Not considered to be medical devices). Including parts of the

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			system such as regulators and valves
*MD 1200 - Devices for imaging			
- *MD 1201 - Imaging devices utilising ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1202 - Imaging devices utilising non-ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	
*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)	Annex II Annex V	
- *MD 1302 - Monitoring devices of vital physiological parameters	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex II Annex V	
*MD 1400 - Devices for radiation therapy and thermo therapy			
- *MD 1401 - Devices utilising ionizing radiation	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1402 - Devices utilising non-ionizing radiation	Full quality assurance system	Annex II Annex V	

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	Production quality assurance		
- *MD 1403 - Devices for hyperthermia / hypothermia	Full quality assurance system Production quality assurance	Annex II Annex V	
- *MD 1404 - Devices for (extracorporal) shock-wave therapy (lithotripsy)	Full quality assurance system Production quality assurance	Annex II Annex V	

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 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 absorbed	
*MDS 7010 - Medical devices incorporating software /utilising software /controlled by software	