Medicines & Healthcare products Regulatory Agency

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Approved Body: TUV Rheinland UK Ltd 2571

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 III of	Limitations

		Schedule 2A to the Medical Devices Regulations 2002]	
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;	Annex II; Annex V;	

	Product quality assurance	Annex VI	
MD 0107 – Contraceptive medical devices	Full quality assurance system; Production quality assurance; Product quality assurance	Annex II; Annex V; Annex VI	Excluding long-term invasive devices used for contraception or prevention of sexually transmitted diseases
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 0110 – Non-active medical devices for ingestion	Full quality assurance system; Production quality assurance; 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	Excluding heart valves introduced into the body by open heart surgery
MD 0202 – Non-active orthopaedic implants	Full quality assurance system; Production quality assurance; Product quality assurance	Annex II; Annex V; Annex VI	Excluding implants for full replacement of the hip, shoulder, knee
MD 0203 – Non-active functional implants	Full quality assurance system; Production quality assurance; Product quality assurance	Annex II; Annex V; Annex VI	Excluding implants for contraception or prevention of sexually transmitted diseases
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 and implants containing silicone with cosmetic claims

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	
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	Full quality assurance system;	Annex II; Annex V;	

	Production quality assurance; Product quality assurance	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	Excluding hyperbaric therapy chambers
MD 1103 – Devices for stimulation or inhibition	Full quality assurance system; Production quality assurance; Product quality assurance	Annex II; Annex V; Annex VI	Excluding active devices for brain stimulation
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;	Annex II; Annex V;	

	Production quality assurance; Product quality assurance	Annex VI	
MD 1110 – 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 1111 – Software	Full quality assurance system; Production quality assurance; Product quality assurance	Annex II; Annex V; Annex VI	
MD 1112 – Parts incorporated within Medical gas supply systems	Full quality assurance system; Production quality assurance; Product quality assurance	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.
MD 1200 – Devices for imaging			
MD 1201 – Imaging devices utilising ionizing radiation	Full quality assurance system; Production quality assurance; Product quality assurance	Annex II; Annex V; 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	Full quality assurance system; Production quality assurance; Product quality assurance	Annex II; Annex V; Annex VI	

MD 1302 – Monitoring devices of vital physiological parameters	Full quality assurance system; Production quality assurance; 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 (extracorporal) 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 – Medica 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	For active medical devices only

MDS 7006 – Medical devices in sterile condition	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, thermic sterilisation with dry heat, sterilisation by liquid chemical sterilants
MDS 7008 – Medical devices utilising nanomaterials	
MDS 7009 – Medical devices utilising biological active coating and/or materials or being wholly or mainly absorbed	
MDS 7010 – Medical devices incorporating software / utilising software / controlled by software	