



BSI Assurance UK Ltd  
Kitemark Court  
Davy Avenue  
Milton Keynes  
MK5 8PP  
United Kingdom

**Approved Body:** BSI Assurance UK Ltd 0086

**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 I of Schedule 2A to the Medical Devices Regulations 2002]	Limitations
<b>MD 0100 - General non-active, non-implantable medical devices</b>			
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	Full quality assurance system Production quality assurance 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	Full quality assurance system Production quality assurance Product quality assurance	Annex II Annex V Annex VI	
<b>MD 0200 - Non-active implants</b>			
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	
<b>MD 0300 - Devices for wound care</b>			
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	
<b>MD 0400 - Non-active dental devices and accessories</b>			
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	
<b>MD 1000 - Medical Devices, Active</b>			

<b>MD 1100 - General active medical devices</b>			
MD 1101 - Devices for extra-corporal circulation, infusion and haemopheresis	Full quality assurance system Production quality assurance 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	Full quality assurance system Production quality assurance 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	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.
<b>MD 1200 - Devices for imaging</b>			
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	
<b>MD 1300 - Monitoring devices</b>			

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	
<b>MD 1400 - Devices for radiation therapy and thermo therapy</b>			
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	

<b>Horizontal technical competence</b>	<b>Limitations</b>
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 7003 - Medical devices incorporating derivatives of human blood according to UK Medical Devices Regulations 2002	
MDS 7004 - Medical devices referencing The Supply of Machinery (Safety) Regulations 2008	
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, sterilisation with liquid chemical sterilising agents, thermic sterilisation with dry heat, sterilisation with supercritical carbon dioxide, sterilisation with nitrogen dioxide, sterilisation with chlorine dioxide.
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	