



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

TUV Rheinland UK Ltd
Friars Gate (3rd Floor)
1011 Stratford Road
Shirley
Solihull
B90 4BN
United Kingdom

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 |
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| | | 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; | |

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| | 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 |

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| 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; | |

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| | 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; | |

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| | 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 | |

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| 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 (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 – 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 |

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| 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 | |