Medicines & Healthcare products Regulatory Agency

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**Approved Body:** Intertek Medical Notified Body UK Ltd 8532

**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;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0102 – Non-active devices for injection, infusion, transfusion and dialysis | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0103 – Non-active orthopaedic and rehabilitation devices | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0104 – Non-active medical devices with measuring function | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0105 – Non-active ophthalmologic devices | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0106 – Non-active instruments | Full quality assurance system;<br>Production quality assurance; | Annex II;<br>Annex V; | |

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| | Product quality assurance | Annex VI | |
| MD 0107 – Contraceptive medical devices | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | Limited to male condoms only. |
| MD 0108 – Non-active medical devices for disinfecting, cleaning, rinsing | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| **MD 0200 – Non-active implants** | | | |
| MD 0201 – Non-active cardiovascular implants | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0202 – Non-active orthopaedic implants | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0203 – Non-active functional implants | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0204 – Non-active soft tissue implants | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| **MD 0300 – Devices for wound care** | | | |
| MD 0301 – Bandages and wound dressings | Full quality assurance system;<br>Production quality assurance; | Annex II;<br>Annex V; | |

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| | Product quality assurance | Annex VI | |
| MD 0302 – Suture material and clamps | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0303 – Other medical devices for wound care | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| **MD 0400 – Non-active dental devices and accessories** | | | |
| MD 0401 – Non-active dental equipment and instruments | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0402 – Dental materials | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 0403 – Dental implants | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| **MD 1100 – General active medical devices** | | | |
| MD 1101 – Devices for extra-corporal circulation, infusion and haemopheresis | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1102 – Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia | Full quality assurance system;<br>Production quality assurance; | Annex II;<br>Annex V; | |

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| | Product quality assurance | Annex VI | |
| MD 1103 – Devices for stimulation or inhibition | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1104 – Active surgical devices | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1105 – Active ophthalmologic devices | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1106 – Active dental devices | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1107 – Active devices for disinfection and sterilisation | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1108 – Active rehabilitation devices and active prostheses | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1109 – Active devices for patient positioning and transport | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1111 – Software | Full quality assurance system;<br>Production quality assurance; | Annex II;<br>Annex V; | |

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| | Product quality assurance | Annex VI | |
| MD 1112 – Parts incorporated within Medical gas supply systems | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | Excluding medical gas pipelines (Not considered to be medical devices).<br><br>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;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1202 – Imaging devices utilising non-ionizing radiation | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| **MD 1300 – Monitoring devices** | | | |
| MD 1301 – Monitoring devices of non-vital physiological parameters | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1302 – Monitoring devices of vital physiological parameters | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| **MD 1400 – Devices for radiation therapy and thermotherapy** | | | |
| MD 1401 – Devices utilising ionizing radiation | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |

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| MD 1402 – Devices utilising non-ionizing radiation | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| MD 1403 – Devices for hyperthermia / hypothermia | Full quality assurance system;<br>Production quality assurance;<br>Product quality assurance | Annex II;<br>Annex V;<br>Annex VI | |
| **Horizontal technical competence** | | | **Limitations** |
| 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), others (need to be specified). |
| MDS 7010 – Medical devices incorporating software / utilising software / controlled by software | | | |