Medicines & Healthcare products Regulatory Agency

MHRA

DEKRA Certification UK Ltd.
Oxford Road,
Stokenchurch,
High Wycombe,
HP14 3SZ

**Approved Body:** DEKRA Certification UK Ltd 8505

**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 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<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 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 | |

| 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 0106 - Non-active instruments | Full quality assurance system<br>Production quality assurance<br>Product quality assurance | Annex II<br>Annex V<br>Annex VI | |
| - *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 0109 - Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) | 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<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 0403 - Dental implants | 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 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 7006 - Medical devices in sterile condition | |
| *MDS 7009 - Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed | |