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 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 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 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	
- *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	
***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	

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	