# Schedule of Accreditation

**issued by**

# United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

| | | |
|---|---|---|
| UKAS MANAGEMENT SYSTEMS<br>**23158**<br>**Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification** | **DEKRA Certification UK Ltd**<br>**Issue No:** 006 **Issue date:** 10 April 2025 | |
| | **Stokenchurch House**<br>**Oxford Road**<br>**Stokenchurch**<br>**HP14 3SX** | **Contact: Danielle Pixton**<br>**Tel: +44 (0)1494 480500**<br>**Email: danielle.pixton@dekra.com**<br>**Website: www.dekra.com** |

## SUMMARY OF ACCREDITED SCOPE

**Accredited to provide certification of the following Management Systems Standards and related Sector Schemes as detailed in this schedule:**

- **Medical Devices - Quality Management Systems (MD-QMS) to ISO 13485: 2016**

**23158**

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to provide management
systems certification

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## DEKRA Certification UK Ltd

**Issue No:** 006 **Issue date:** 10 April 2025

| KEY LOCATION ADDRESS | MD-QMS |
|---|---|
| DEKRA Certification UK Ltd<br>Stokenchurch House<br>Oxford Road<br>Stokenchurch | ✓ |

This Certification Body has demonstrated to UKAS that it has the systems and processes in place to provide the capability to manage and issue accredited management systems certification only in the country in which it is established for the standards and scopes detailed on this schedule, unless specifically detailed in the individual Management System scope table *(denoted by *)*.

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## MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

**In accordance with ISO/IEC 17021-1: 2015**

**ISO 13485: 2016 Certification**

| **IAF Mandatory Scopes of Accreditation Scope Reference** | **Technical Area** |
|---|---|
| **1.1 Non-active Medical Devices** | General non-active, non-implantable medical devices |
| | Non-active implants |
| | Devices for wound care |
| | Non-active dental devices and accessories |
| | Non-active medical devices other than specified above |
| **1.2 Active Medical Devices (Non-Implantable)** | General active medical devices |
| | Devices for imaging |
| | Monitoring devices |
| | Devices for radiation therapy and thermo therapy |
| | Active (non-implantable) medical devices other than specified above |
| **1.3 Active Implantable Medical Devices** | General active implantable medical devices |
| | Implantable medical devices other than specified above |

## MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

**In accordance with ISO/IEC 17021-1: 2015**

**ISO 13485: 2016 Certification**

| | |
|---|---|
| **1.4 In Vitro Diagnostic Medical Devices (IVD)** | Reagents and reagent products, calibrators and control materials for:<br>• Clinical Chemistry<br>• Immunochemistry (immunology)<br>• Haematology /Haemostasis /Immunohematology<br>• Microbiology<br>• Infection Immunology<br>• Histology/cytology<br>• Genetic Testing |
| | In vitro diagnostic instruments and software |
| | IVD medical devices other than specified above |
| **1.5 Sterilisation Method for Medical Devices** | Ethylene oxide gas sterilisation (EOG) |
| | Moist heat |
| | Aseptic processing |
| | Radiation sterilisation (e.g. gamma, x-ray, electron beam) |
| | Low temperature steam and formaldehyde sterilisation |
| | Thermic sterilisation with dry heat |
| | Sterilisation with hydrogen peroxide |
| | Sterilisation method other than specified above |

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**In accordance with ISO/IEC 17021-1: 2015**

**ISO 13485: 2016 Certification**

| | |
|---|---|
| **1.6 Devices Incorporating/Utilising Specific Substances/Technologies** | Medical devices incorporating medicinal substances |
| | Medical devices utilising tissues of animal origin |
| | Medical devices incorporating derivatives of human blood |
| | Medical devices utilising micromechanics |
| | Medical devices utilising nanomaterials |
| | Medical devices utilising biological active coatings and/or materials being wholly or mainly absorbed |

END