


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>24801</b> Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	<b>LNE-GMED UK Limited</b>	
	Issue No: 003    Issue date: 05 April 2024	
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### 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**

KEY LOCATION ADDRESS	MD-QMS
HO	✓

This Certification Body has demonstrated to UKAS that it has the systems and processes in place to provide the competence and capability, including understanding of local requirements, to manage and issue accredited management systems certification in the country in which it is established and in any other country, 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
<b>1.1 Non-active Medical Devices</b>	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
<b>1.2 Active Medical Devices (Non-Implantable)</b>	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
<b>1.3 Active Implantable Medical Devices</b>	General active implantable medical devices
	Implantable medical devices other than specified above



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IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area
<b>1.4 In Vitro Diagnostic Medical Devices (IVD)</b>	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (immunology) Haematology /Haemostasis /Immunoematology Microbiology Infection Immunology Histology/cytology Genetic Testing
	In vitro diagnostic instruments and software
	IVD medical devices other than specified above
<b>1.5 Sterilisation Method for Medical Devices</b>	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 those specified above	



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IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area
<b>1.6 Devices Incorporating/Utilising Specific Substances/Technologies</b>	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
	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above
<b>1.7 Parts or Services</b>	Raw materials
	Components
	Subassemblies
	Calibration services*
	Distribution services
	Maintenance services
	Transportation services
	Other services
<b>END</b>	