Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8175

Accredited to
ISO/IEC 17021-1: 2015
to provide management
systems certification

EUROFINS E&E CML LIMITED

Issue No: 006 **Issue date:** 23 July 2024

Newport Business Park
New Port Road
Ellesmere Port
CH65 4LZ
United Kingdom

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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:

- **Quality Management Systems (QMS) to ISO 9001: 2015**
- **Medical Devices - Quality Management Systems (MD-QMS) to ISO 13485: 2016**

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KEY LOCATION ADDRESS	QMS
Newport Business Park New Port Road Ellesmere Port CH65 4LZ United Kingdom	✓

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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QUALITY MANAGEMENT SYSTEMS

In accordance with ISO/IEC 17021-1: 2015

ISO 9001: 2015 Certification

Accreditation Scope Reference (as defined in IAF ID 1)	**Full / Limited Accreditation**	**Extent of Scope**
IAF 17 Basic metals and fabricated metal products	Full	
IAF 18 Machinery and equipment	Full	
IAF 19 Electrical and optical equipment	Full	
END		

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
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

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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
1.4 In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators, and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/ Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
	IVD Instruments and software
	IVD medical devices other than specified above
1.5 Sterilisation Method for Medical Devices	Ethylene oxide gas (EOG)
	Moist heat
	Radiation sterilisation (e.g. gamma, x-ray, electron beam)
	Low temperature steam and formaldehyde sterilisation
	Thermic sterilisation with dry heat
	Sterilisation with hydrogen peroxide

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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**
1.7 Parts and services	Raw materials
	Components
	Subassemblies
	Calibration services
	Distribution services
	Maintenance services
	Transportation services
	Other services

END