Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

UKAS MANAGEMENT SYSTEMS **4426** Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	**UL LLC** **Issue No:** 020 **Issue date:** 01 February 2024	
	333 Pfingsten Road **Northbrook** **IL 60062-2096** **USA**	**Contact: Benjamin Wulf** **Tel: +1 360 817 5664** **Email: Benjamin.Wulf@ul.com**

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**

4426

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

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

UL LLC

Issue No: 020 **Issue date:** 01 February 2024

KEY LOCATION ADDRESS	QMS	MD-QMS
333 Pfingsten Road Northbrook IL 60062-2096 USA	✓	✓
12 Laboratory Drive Research Triangle Park NC 27709 USA	✓	✓

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 *)*.

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 4 Textiles and textile products	Limited	Weaving of textiles, manufacture of other technical and industrial textiles related to medical devices
IAF 12 Chemicals, chemical products and fibres	Limited	Manufacture of plastics and synthetic rubber in primary form. Manufacture of other chemical products related to medical devices
IAF 13 Pharmaceuticals	Limited	Manufacture of basic pharmaceutical products and pharmaceutical preparations related to medical devices
IAF 14 Rubber and plastic products	Limited	Manufacture of rubber and plastic products. Manufacture of plastic plates, sheets, tubes, profiles and packing goods related to medical devices
IAF 19 Electrical and optical equipment	Limited	Manufacture of irradiation, electromedical and electrotherapeutic equipment. Manufacture of electronic components, boards and loaded boards. Manufacture of electric lighting equipment related to medical devices
IAF 22 Other transport equipment	Limited	Manufacture of wheelchairs related to medical devices
IAF 23 Manufacturing not elsewhere classified	Limited	Manufacture of medical and dental instruments and supplies. Manufacture of furniture and mattresses related to medical devices

4426 Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	**Schedule of Accreditation** **issued by** **United Kingdom Accreditation Service** 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK **UL LLC** **Issue No:** 020 **Issue date:** 01 February 2024

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 29 Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	Limited	Wholesale and retail of pharmaceuticals related to medical devices
IAF 33 Information technology	Limited	Computer programming, consultancy and related activities related to medical devices
IAF 34 Engineering services	Limited	Technical testing and analysis. Specialised design activities related to medical devices
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
	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

4426 Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	**Schedule of Accreditation** **issued by** **United Kingdom Accreditation Service** 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK **UL LLC** **Issue No:** 020 **Issue date:** 01 February 2024

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 • Infection Immunology • Histology/cytology • Genetic Testing
	In vitro diagnostic instruments and software
1.5 Sterilisation Method for Medical Devices	Ethylene oxide gas (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilisation (e.g. gamma, x-ray, electron beam)
	Low temperature steam and formaldehyde sterilisation

4426 Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	**Schedule of Accreditation** **issued by** **United Kingdom Accreditation Service** 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK **UL LLC** **Issue No:** 020 **Issue date:** 01 February 2024

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**
	Thermic sterilisation with dry heat
	Sterilisation with hydrogen peroxide
	Sterilisation method other than specified above

END