


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 4426 Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification	UL LLC Issue No: 019 Issue date: 31 October 2022	
	333 Pfingsten Road Northbrook IL 60062-2096 USA	Contact: Deborah L. Stubbs Tel: +510 319 4173 Email: Deborah.L.Stubbs@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](#)



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KEY LOCATION ADDRESS	QMS	MD-QMS
333 Pfingsten Road Northbrook IL 60062-2096 USA	✓	✓
47173 Benica Street Freemont CA 94538 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 **).



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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 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



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QUALITY MANAGEMENT SYSTEMS

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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		



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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



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MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

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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: <ul style="list-style-type: none"> • Clinical Chemistry • Immunochemistry (immunology) • Haematology /Haemostasis /Immunoematology • 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



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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	