Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

UKAS MANAGEMENT SYSTEMS **8400** **Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification**	**TUV Rheinland UK Ltd** **Issue No:** 004 **Issue date:** 04 November 2025	
	TÜV Rheinland UK **Friars Gate (Third Floor)** **1011 Stratford Road** **Shirley** **Solihull** **B90 4BN**	**Contact: Mr Lee Willison** **Tel: +44 (0)121 796 9400** **E-Mail: Lee.Willison@uk.tuv.com** **Website: https://www.tuv.com/united-kingdom/en**

SUMMARY OF ACCREDITED SCOPE

Product certification for

- **Pressure Equipment (Safety) Regulations 2016, SI 2016 No 1105 as amended**
- **Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001, SI 2001 No 1701 as amended**

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**

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Issue No: 004 **Issue date:** 04 November 2025

KEY LOCATION ADDRESS	MD-QMS
TÜV Rheinland UK Friars Gate (Third Floor) 1011 Stratford Road Shirley Solihull B90 4BN	✓

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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Accreditation for the purpose of UK Approved Body Activity in accordance with UKCA Requirements and UKAS Publication GEN 5				
Directive / Regulation	**Conformity Assessment procedure/ Module/article**	**Category of products or individual products**	**Essential requirements: Product specification /Properties/Standards**	**Location code**
Pressure Equipment (Safety) Regulations 2016, SI 2016 No 1105 as amended	**Conformity assessment procedures in accordance with Regulation 42 of the SI** Schedule 1A Part 11 – Module H Conformity based on full quality assurance	Category III Equipment	Schedule 2, assessment of technical documentation and quality system	

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Directive / Regulation	Conformity Assessment procedure/ Module/article	Category of products or individual products	Essential requirements: Product specification /Properties/Standards	Location code
Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001, SI 2001 No 1701 as amended	Schedule 11 Full quality assurance	The following equipment subject to noise limits Specified in *Schedule 1* and defined in *Schedule 4* of the regulations: • builders' hoists for the transport of goods (combustion-engine driven) • compaction machines (only vibrating and non-vibrating rollers, vibratory plates and vibratory rammers) • compressors (<350 kW) • concrete-breakers and picks, hand-held • construction winches (combustion-engine driven) • dozers (<500 kW) • dumpers (<500 kW) • excavators, hydraulic or rope-operated (<500 kW) • excavator-loaders (<500 kW) • graders (<500 kW) • hydraulic power packs landfill compactors, loader-type with bucket (<500 kW)	Assessment of quality system	

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Directive / Regulation	Conformity Assessment procedure/ Module/article	Category of products or individual products	Essential requirements: Product specification /Properties/Standards	Location code
Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001, SI 2001 No 1701 as amended (cont'd)	Schedule 11 Full quality assurance (cont'd)	The following equipment subject to noise limits Specified in *Schedule 1* and defined in *Schedule 4* of the regulations: (cont'd) • lawnmowers (excluding agricultural and forestry equipment, and multi-purpose devices, the main motorised component of which has an installed power of more than 20 kW) • lawn trimmers/lawn edge trimmers • lift trucks, combustion-engine driven, counterbalanced (excluding "other counterbalanced lift trucks" as defined in Annex I, Item 36, second indent with a rated capacity of not more than 10tonnes) • loaders (<500 kW) • mobile cranes • motor hoes (<3 kW) • paver-finishers (excluding paver-finishers equipped with a high-compaction screed) • power generators (<400 kW) • tower cranes • welding generators	Assessment of quality system	

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

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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 • Infection Immunology • Histology/cytology • 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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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**
1.6 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
	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above

END