Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

UKAS MANAGEMENT SYSTEMS **0172** **Accredited to ISO/IEC 17021-1: 2015 to provide management systems certification**	**TUV SUD BABT UNLIMITED** **Issue No:** 008 **Issue date:** 17 July 2024	
Octagon House **Concorde Way** **Segensworth North** **Fareham** **Hampshire** **PO15 5RL**	**Contact: Mr Mark Pope** **Tel: +44 (0) 796 7581747** **E-Mail: mark.pope@tuvsud.com** **Website: www.tuv-sud.co.uk/babt**	

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**
- **Accreditation for the purpose of UK Approved Body Activity in accordance with UKCA Requirements and UKAS Publication GEN 5**

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KEY LOCATION ADDRESS	QMS
Octagon House Concorde Way Segensworth North Fareham Hampshire PO15 5RL	✓

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 19 Electrical and optical equipment	Limited	Manufacture of electronic components and boards Manufacture of computers and peripheral equipment Manufacture of communication equipment Manufacture of consumer electronics Manufacture of other electrical equipment Repair of electronic and optical equipment Repair of electrical equipment

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Directive / Regulation	Conformity Assessment procedure/ Module/article	Category of products or individual products	Essential requirements: Product specification / Properties/Standards
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
Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001, SI 2001 No 1701 as amended	**Conformity assessment procedures in accordance with** Schedule 11 Full quality assurance	The following equipment subject to noise limits specified in ***Schedule 1*** and defined in ***Schedule 4*** of the regulations: 3 Builders' hoists for the transport of goods (combustion engine driven) 8 Compaction Machines (only vibrating and non-vibrating rollers, vibratory plates and vibratory rammers) 9 Compressors (< 350 kW) 10 Hand-held concrete-breakers and picks 12 Construction winches (combustion engine driven) 16 Dozers ~(< 500 kW) 18 Dumpers (< 500 kW) 20 Excavators, hydraulic or rope-operated (< 500 kW) 21 Excavator-loaders (<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
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	23 Graders (<500 kW) 29 Hydraulic power packs 31 Landfill compactors, loader type with bucket (<500 kW) 32 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) 33 Lawn trimmers/ Lawn edge trimmers 36 Lift trucks, combustion engine driven, counterbalanced (excluding 'other counterbalanced lift trucks' as defined in Schedule 4, Annex 36, second indent with a rated capacity of not more than 10 tonnes) 37 Loaders (< 500 kW) 38 Mobile cranes 40 Motor hoes (< 3kW) 41 Paver-finishers (excluding paver-finishers equipped with a high-compaction screed) 45 Power generators (< 400 kW) 53 Tower cranes 57 Welding Generators	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
Radio Equipment Regulations 2017 as amended	Schedule 4 Module H Conformity Based on Full Quality Assurance	Aeronautical Equipment Base Station for Mobile Network Broadcast (including programme making and outside broadcast) Citizens Band Cordless Telephone Distress/Position indicating beacon Fixed Link Fixed Wireless Access Industrial Scientific and Medical with the scope of the directive Maritime (for non SOLAS vessels only) Mobile (Cellular) Telephone Handsets Paging (Radio Messaging) Private/Professional Mobile Radio, Radar, Radio Frequency Identification (RFID), Radio Local Area Network Satellite earth station (Fixed mobile) Short Range Device Telemetry/Telecommand Ultra wideband applications (including ground probing radar) Wireless Microphone Radio receivers (including broadcast radio and TV receivers) Radiodetermination equipment Radio equipment operating below 9KHz	

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Directive / Regulation	**Conformity Assessment procedure/ Module/article**	**Category of products or individual products**	**Essential requirements: Product specification / Properties/Standards**
Lifts Regulations 2016 SI 2016 No 1093 as amended	Schedule 14 Conformity based on full quality assurance for safety components for lifts (Module H)	Safety components	Schedule 1 assessment of technical documentation and quality system

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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
	Implantable medical devices other than specified above

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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: 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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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 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
1.7 Parts or Services	Raw materials
	Components
	Subassemblies
	Calibration services*
	Distribution services
	Maintenance services
	Transportation services
	Other services

END