

United Kingdom Accreditation Service

ACCREDITATION CERTIFICATE



CERTIFICATION BODY
No. 0043

United Registrar of Systems Ltd

is accredited in accordance with the recognised International Standard
ISO/IEC 17021:2011 - Conformity assessment - Requirements for bodies providing audit and certification of
management systems, for Quality Management Systems (ISO 9001:2008).

This accreditation demonstrates technical competence for a defined scope as detailed in and at the locations
specified in the schedule to this certificate.

The schedule to this certificate is an essential accreditation document and from time to time may be revised and
reissued by the United Kingdom Accreditation Service. The most recent issue of the schedule of accreditation,
which bears the same accreditation number as this certificate, is available from the UKAS website
www.ukas.com.

This accreditation is subject to continuing conformity
with United Kingdom Accreditation Service requirements. The absence of a schedule on the UKAS website
indicates that the accreditation is no longer in force.

Accreditation Manager, United Kingdom Accreditation Service

Initial Accreditation date
8 September 2008

This certificate issued on
17 June 2015

UKAS is appointed as the sole national accreditation body for the UK by The Accreditation Regulations 2009 (SI No 3155/2009) and
operates under a Memorandum of Understanding (MoU) with the Department for Business, Innovation and Skills (BIS).



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Accredited to
ISO/IEC 17021:2011 to provide
quality management systems
certification

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

United Registrar of Systems Ltd.
Issue No: 070 Issue date: 22 February 2016

BS EN ISO 13485:2003 & ISO 13485:2012 Certification

IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area	Extent of Scope
Non-active Medical Devices	General non-active, non-implantable medical devices	<ul style="list-style-type: none"> • Non-active devices for anaesthesia, emergency and intensive care • Non-active devices for injection, infusion, transfusion and dialysis • Non-active orthopaedic and rehabilitation devices • Non-active instruments • Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
	Non-active implants	<ul style="list-style-type: none"> • Non-active orthopaedic implants
	Devices for wound care	<ul style="list-style-type: none"> • Bandages and wound dressings • Suture material and clamps • Other medical devices for wound care
	Non-active dental devices and accessories	<ul style="list-style-type: none"> • Non-active dental devices/equipment and instruments • Dental products • Dental implants



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IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area	Extent of Scope
Active Medical Devices (Non-Implantable)	General medical devices	<ul style="list-style-type: none"> • Devices for extra-corporal circulation, infusion and haemopheresis • Respiratory devices • Devices for stimulation or inhibition • Active surgical devices • Active dental devices • Active devices for sterilisation and disinfection • Active rehabilitation devices and prostheses • Active devices for patient positioning and transport • Software
	Devices for imaging	<ul style="list-style-type: none"> • Devices utilizing ionizing rays • Devices utilizing non-ionizing rays
	Monitoring devices	<ul style="list-style-type: none"> • Monitoring devices of non-vital physiological parameters • Monitoring devices of vital physiological parameters
	Devices for radiation therapy and thermo therapy	<ul style="list-style-type: none"> • Devices utilising ionizing radiation • Devices utilising non-ionizing radiation • Devices for hyperthermia/hypothermia • Devices for (extracorporal) shockwave therapy (lithotripsy)



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Active Implantable Medical devices	General active implantable medical devices	<ul style="list-style-type: none"> • Active implantable medical devices for stimulation / inhibition • Active implantable medical devices delivering drugs or other substances • Active implantable medical devices substituting or replacing organ functions
Sterilisation Method for Medical devices	Ethylene oxide gas (EOG) Moist heat	
	Aseptic processing	
	Radiation sterilisation (e.g. gamma, x-ray, electron beam)	
In Vitro Diagnostic Medical Devices (IVD)	In Vitro Diagnostic Instruments and software	
	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Haematology /Haemostasis /Immunohematology Immunochemistry Microbiology Infection Immunology Histology/cytology Genetic Testing	



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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	
END		



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United Registrar of Systems Ltd is recorded as issuing UKAS accredited certificates to organisations in the countries listed below. This list is current at the time of issue of this schedule.

Australia	Austria	Bangladesh	Belarus
Bhutan	Bosnia and Herzegovina	Brunai Darussalem	Bulgaria
Burundi	Cambodia	Canada	China PR
Croatia	Cyprus	Czech Republic	Dem Rep of Congo
Denmark	Egypt	Eire	France
Georgia	Germany	Gibraltar	Hong Kong
Hungary	India	Indonesia	Iraq
Italy	Israel	Japan	Jordan
Kenya	Kingdom of Bahrain	Kingdom Saudi Arabia	Korea
Kuwait	Lao PDR	Lebanon	Libya
Luxembourg	Malaysia	Monaco	Myanmar
Nepal	Netherlands	New Zealand	Nigeria
Oman	Pakistan	Poland	Portugal
Qatar	Romania	Republic of Kazakhstan	Republic of Kosovo
Republic of Macedonia	Russia	Rwanda	Serbia
Singapore	Slovakia	South Africa	Spain
Somalia	Sri Lanka	Suriname	Sweden
Switzerland	Taiwan	Thailandn	Tunisia
Turkey	UAE	Uganda	Ukraine
United Kingdom	USA	Vietnam	Zambia