


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 0043 Accredited to ISO/IEC 17021-1:2015 to provide quality management systems certification	United Registrar of Systems Ltd. Issue No: 074 Issue date: 30 June 2017	
	Derby Manor Derby Road Bournemouth Dorset BH1 3QB	Contact: Mr D Riggs Tel: +44 (0)1202 552 153 Fax: +44 (0)1202 290 716 E-Mail: info@urs-certification.co.uk Website: www.urs-certification.co.uk

Locations where certification activities covered by the above Accreditation Standard are undertaken	
Derby Manor Derby Road Bournemouth Dorset BH1 2E United Kingdom Lead Office for EN 9104-001:2013 Aerospace Sector Scheme	F 3 Sector 6 Noida 201301 India



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DETAIL OF ACCREDITATION

ISO 9001:2008 and ISO 9001:2015 Certification		
European Co-operation for Accreditation Scope Reference	Full/Limited Accreditation	Extent of Scope
EA 1 Agriculture, fishing	Limited	Growing of crops; market gardening; horticulture, farming of cattle, farming of swine. Including HACCP in accordance with the principles of Codex Alimentarius (URS document AN 34) in association with ISO 9001:2008 for a limited scope associated with food chain related activity.
EA 3 Food products, beverages and tobacco	Full	Including HACCP in accordance with the principles of Codex Alimentarius (URS document AN 34) in association with ISO 9001:2008
EA 4 Textiles and textile products	Full	
EA 5 Leather and leather products	Full	
EA 6 Wood and wood products	Full	
EA 7 Pulp, paper and paper products	Full	
EA 8 Publishing companies	Full	
EA 9 Printing companies	Full	
EA 12 Chemicals, chemical products and fibres	Limited	Manufacture of chemicals, chemical products and man-made fibres but excluding explosives and pharmaceutical products
EA 13 Pharmaceuticals	Limited	Manufacture of botanical products. Compounding, supply and delivery of medically prescribed treatment, including pharmaceutical, medical and ancillary products and services



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ISO 9001:2008 and ISO 9001:2015 Certification

European Co-operation for Accreditation Scope Reference	Full/Limited Accreditation	Extent of Scope
EA 14 Rubber and plastic products	Full	
EA 15 Non-metallic mineral products	Full	
EA 16 Concrete, cement, lime, plaster etc	Full	
EA 17 Basic metals and fabricated metal products	Full	
EA18 Machinery and equipment	Full	
EA 19 Electrical and optical equipment	Full	
EA 21 Aerospace	Full	
EA 22 Other transport equipment	Limited	Other transport equipment - to include: 1. Manufacture of motor vehicles. 2. Manufacture of bodies (coachwork) for motor vehicles: manufacture of trailers and semi-trailers. 3. Manufacture of parts and accessories for motor vehicles and their engines. 4. Manufacture of invalid carriages.
EA 23 Manufacturing not elsewhere classified	Full	
EA 24 Recycling	Limited	Recycling of non-hazardous materials
EA 27 Water supply	Limited	Collection and purification of drinking water
EA 28 Construction	Full	



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European Co-operation for Accreditation Scope Reference	Full/Limited Accreditation	Extent of Scope
EA 29 Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	Full	Including HACCP in accordance with the principles of Codex Alimentarius (URS document AN 34) in association with ISO 9001:2000 for a limited scope associated with food and food chain related products only PAS 43:2002 - Safe working of vehicle recovery and breakdown operators
EA 30 Hotels and restaurants	Full	Including HACCP in accordance with the principles of Codex Alimentarius (URS document AN 34) in association with ISO 9001:2000 associated with food and food chain related activities only
EA 31 Transport, storage and communication	Full	Including PAS 43:2002 - Safe working of vehicle recovery and breakdown operators
EA 32 Financial intermediation; real estate; renting	Full	
EA 33 Information technology	Full	
EA 34 Engineering services	Full	
EA 35 Other services	Full	
EA 36 Public Administration	Full	
EA 37 Education	Full	
EA 38 Health and social work	Full	



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European Co-operation for Accreditation Scope Reference	Full/Limited Accreditation	Extent of Scope
EA 39 Other social services	Limited	Refuse disposal and similar activities Activities of business, employers and professional organisations Library, archives, museums and other cultural activities Sporting activities Other service activities (washing, hairdressing, funeral directors)

END

Sector Scheme Accreditation

Aerospace Sector Certification Scheme
Lead Office for EN 9104-001:2013 Aerospace Sector Scheme
Derby Manor
Derby Road
Bournemouth
Dorset
BH1 3QB
United Kingdom

EN 9104-001:2013 for the certification of clients to AS, EN or JISQ 9100 including 2016 version and AS, EN or JISQ 9120 including 2016 version

END



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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 fertzation (IVFO 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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IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area	Extent of Scope
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 /Immunochemistry Immunochemistry Microbiology Infection Immunology Histology/cytology Genetic Testing	



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IAF Mandatory Scopes of Accreditation Scope Reference	Technical Area	Extent of Scope
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	
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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