



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: Lloyd’s Register Quality Assurance, Inc.

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LOCATION A

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| SCC File Number: | 08015 |
| Accreditation Standards: | ISO/IEC 17021-1:2015 IAF MD1, MD2, MD5 |
| Initial Accreditation Date: | 1997-09-12 |
| Reaccreditation Date: | 2014-04-11 |
| Accreditation Expiry Date: | 2018-04-11 |

Additional Critical/Key Locations:

| Location | Country | Address | City |
|----------|----------------|---|------------|
| B | United Kingdom | LRQA, Ltd. 1 Trinity Park Bickenhill Lane Birmingham B37 7ES UK | Birmingham |



I: Quality Management Systems Program

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| Base program: | Quality Management Systems (QMS) | |
| Additional accreditation standards | ISO/IEC TS 17021-3:2013 IAF MD3 | |
| Certification standard: | ISO 9001:2008 and ISO 9001:2015 | |
| Industry sector program(s): | | |
| Locations: | A-B | |
| Certification Body's technical scope of accreditation to certify organizations by IAF/NACE codes: | 1 Agriculture, Forestry and Fishing 2 Mining and Quarrying 3 Food Products, Beverages and Tobacco 4 Textiles and Textile Products 5 Leather and Leather Products 6 Wood and Wood Products 7 Pulp, Paper and Paper Products 8 Publishing Companies 9 Printing Companies 10 Manufacture of Coke and Refined Petroleum Products 11 Nuclear fuel 12 Chemicals, Chemical Products and Fibres 13 Pharmaceuticals 14 Rubber and Plastic Products 15 Non-Metallic Mineral Products 16 Concrete, Cement, Lime, Plaster, etc. 17 Basic Metals and Fabricated Metal Products 18 Machinery and Equipment 19 Electrical and Optical Equipment 20 Shipbuilding 21 Aerospace 22 Other Transport Equipment 23 Manufacturing Not Elsewhere Classified 24 Recycling 25 Electricity Supply 26 Gas Supply 27 Water Supply 28 Construction 29 Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 30 Hotels and Restaurants 31 Transport, Storage and Communication 32 Financial Intermediation; Real Estate; Renting 33 Information Technology 34 Engineering Services | |



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| | 35 | Other Services |
| | 36 | Public Administration |
| | 37 | Education |
| | 38 | Health and Social Work |
| | 39 | Other Social Services |

II: Medical Devices Quality Management Systems Program

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| Base program: | Medical Devices Quality Management Systems | |
| Additional accreditation standards | GD207; GD210; GD211; Q90R0 IAF MD9 | |
| Certification standards: | ISO 13485:2003 under CMDCAS ISO 13485:2003 | |
| Locations: | A-B | |
| Certification Body's main technical areas: (IAF MD 8 & MD 9) | Non-active Medical Devices | <ul style="list-style-type: none"> • 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 |
| | Active Medical Devices (Non-Implantable) | <ul style="list-style-type: none"> • 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 |
| | Active Implantable Medical Devices | <ul style="list-style-type: none"> • General active implantable medical devices • implantable medical devices other than specified above |
| | In Vitro Diagnostic Medical Devices (IVD) | <ul style="list-style-type: none"> • Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> – Clinical Chemistry – Immunochemistry (Immunology) – Haematology/Haemostasis/Immunoematology – Microbiology – Infectious Immunology – Histology/Cytology – Genetic Testing • In Vitro Diagnostic Instruments and software |
| | Sterilization Method for Medical Devices | <ul style="list-style-type: none"> • Ethylene oxide gas sterilization (EOG) • Moist heat |



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| | | <ul style="list-style-type: none">• Aseptic processing• Radiation sterilization (e.g. gamma, x-ray, electron beam) |
| | Devices incorporating/utilizing specific substances/technologies | <ul style="list-style-type: none">• Medical devices incorporating medicinal substances• Medical devices utilizing tissues of animal origin• Medical devices incorporating derivatives of human blood• Medical devices utilizing micromechanics• Medical devices utilizing nanomaterials• Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed |

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to Lloyd's Register Quality Assurance, Inc. The original version is available in the Directory of Accredited Management Systems Certification Bodies on the SCC website at www.scc.ca.

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Vice President, Accreditation Services
Date: 2017-05-21