MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

La présente portée d'accréditation existe également en français et est publiée séparément.

Accredited Legal Entity: **DQS Medizinprodukte GmbH**

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LOCATION A

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SCC File Number:	08047
Accreditation Standards:	ISO/IEC 17021-1:2015 IAF MD 1:2023 IAF MD 2:2023 IAF MD 4:2023 IAF MD 5:2023 IAF MD 9:2023 IAF MD 23:2023 Related MSAP bulletins
Initial Accreditation:	2011-01-24
Most Recent Accreditation:	2023-03-02
Accreditation Valid to:	2027-01-24

Additional Fixed Office Locations (FOL):

See the address of the above legal entity. No other location is included in the accreditation.

Medical Device Management Systems Program

Base program:	Medical Device Management Systems (MDMS)
Additional accreditation standards	IAF MD 9:2023
Certification standards:	ISO 13485:2016
Locations:	A

Main Technical Areas	Technical Areas
Non-active Medical Devices (IAF MD 8 Table 1.1)	• 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 (Non-Implantable) Medical Devices (IAF MD 8 Table 1.2)	• 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
In Vitro Diagnostic Medical Devices (IVD) (IAF MD 8 Table 1.4)	• Reagents and reagent products, calibrators and control materials for: – Clinical Chemistry – Immunochemistry (Immunology) – Haematology/Haemostasis/Immunohematology – Microbiology – Infectious Immunology – Histology/Cytology – Genetic Testing • In Vitro Diagnostic Instruments and software • IVD medical devices other than specified above
Sterilization Method for Medical Devices (IAF MD 8 Table 1.5)	• Ethylene oxide gas sterilization (EOG) • Moist heat • Aseptic processing • Radiation sterilization (e.g. gamma, x-ray, electron beam) • Sterilization method other than specified above
Devices incorporating/	• Medical devices incorporating medicinal substances • Medical devices utilizing tissues of animal origin

utilizing specific substances/ technologies (IAF MD 8 Table 1.6)	• 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 • Medical devices incorporating or utilizing specific substances/technologies/ elements, other than specified above
Parts and Services (IAF MD 8 Table 1.7)	• Raw materials • Components • Subassemblies • Calibration services • Distribution services • Maintenance services • Transportation services • Other services

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to DQS Medizinprodukte GmbH. The original version is available in the Directory of Accredited Management Systems Certification Bodies on the SCC website at scc-ccn.ca.

Elias Rafoul
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