MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

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

Accredited Legal Entity: **TÜV SÜD America Inc.**

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LOCATION A

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To ensure compliance with the Official Languages Act, the Standards Council of Canada (SCC) translated proprietary content from French to English when it was not available in English. In case of discrepancies between the English and French versions, the original version prevails.

SCC File Number:	08023
Accreditation Standards:	ISO/IEC 17021-1:2015 ISO/IEC 17021-3:2017 IAF MD 1:2023 IAF MD 2:2023 IAF MD 4:2023 IAF MD 5:2023 IAF MD 9: 2023 Related MSAP bulletins
Initial Accreditation:	2001-08-03
Most Recent Accreditation:	2025-06-12
Accreditation Valid to:	2027-08-03

Additional Fixed Office Locations (FOL):

Certification activities carried out by the above-mentioned legal entity in the following locations are included in the accreditation:

Location	Country	Address	City
B	Germany	TÜV SÜD Product Services GmbH Ridlerstrasse 65 Munich Germany 80339	Munich

I: Quality Management Systems Program

Base program:	Quality Management Systems (QMS)
Additional accreditation standards	ISO/IEC 17021-3:2017 IAF MD 5:2023
Certification standard:	ISO 9001:2015 ISO 9001:2015/Amd 1:2024
Locations:	A, B, C
Certification Body's technical scope of accreditation to certify organizations by IAF codes:	3 Food Products, Beverages and Tobacco 4 Textiles and Textile Products 5 Leather and Leather Products 9 Printing Companies 12 Chemicals, Chemical Products and Fibres 13 Pharmaceuticals 14 Rubber and Plastic Products 15 Non-Metallic Mineral Products 17 Basic Metals and Fabricated Metal Products 18 Machinery and Equipment 19 Electrical and Optical Equipment 28 Construction 29 Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 33 Information Technology 34 Engineering Services 35 Other Services

II: 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, B, C
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
Active Implantable Medical Devices (IAF MD 8 Table 1.3)	• General active implantable medical devices • 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) • Low temperature steam and formaldehyde sterilization • Thermic sterilization with dry heat • Sterilization with hydrogen peroxide • Sterilization method other than specified above
Devices incorporating/ utilizing specific	• Medical devices incorporating medicinal substances • Medical devices utilizing tissues of animal origin • Medical devices incorporating derivatives of human blood • Medical devices utilizing micromechanics

substances/ technologies (IAF MD 8 Table 1.6)	• 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

Main Technical Areas	**Technical Areas**
Parts and Services (IAF MD 8 Table 1.7)	• Raw materials • Components • Subassemblies • Calibration services* • Distribution services • Maintenance services • Transportation services • Other services

*Organizations providing calibration services should be accredited to ISO/IEC 17025.

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

Elias Rafoul
Vice-President, Accreditation Services
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