MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

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

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LOCATION A

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SCC File Number:	08023
Accreditation Standards:	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD4, MD5, MD 9, MD11 all where applicable
Initial Accreditation:	2001-08-03
Most Recent Accreditation:	2022-07-18
Accreditation Valid to:	2024-09-03

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
C	USA	TÜV SÜD America Inc.	New Brighton

Location	Country	Address	City
		141 14th St NW New Brighton, MN 55112	

I: Quality Management Systems Program

Base program:	Quality Management Systems (QMS)
Additional accreditation standards	ISO/IEC 17021-3:2017
Certification standard:	ISO 9001:2015
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 9:2017
Certification standards:	ISO 13485:2016
Locations:	A, B, C

Certification Body's main technical areas:	Non-active Medical Devices	• 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)	• 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	• General active implantable medical devices • implantable medical devices other than specified above
	In Vitro Diagnostic Medical Devices (IVD)	• 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	• 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/utilizing specific substances/technologies	• 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 • Medical devices incorporating or utilizing specific substances/technologies/ elements, other than specified above
	Parts and Services	• 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 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.ca.

Elias Rafoul
Vice-President, Accreditation Services
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