



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: TÜV SÜD America Inc.
Contact Name: Arie Henkin
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LOCATION A

Address: 10 Centennial Drive
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SCC File Number:	08023
Accreditation Standards:	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD3, MD4, MD5, MD11 (where applicable)
Initial Accreditation Date:	2001-08-03
Reaccreditation Date:	2019-03-15
Accreditation Expiry Date:	2023-12-18

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. 10040 Mesa Rim Road	San Diego



Location	Country	Address	City
		San Diego, CA 92121	
D	USA	TÜV SÜD America Inc. 141 14th St NW New Brighton, MN 55112	New Brighton

I: Quality Management Systems Program

Base program:	Quality Management Systems (QMS)	
Additional accreditation standards	ISO/IEC 17021-3:2017	
Certification standard:	ISO 9001:2015 Advanced Surveillance and Recertification Procedures (ASRP) under IAF MD3	
Locations:	A, B, C, D	
Certification Body's technical scope of accreditation to certify organizations by IAF/NACE 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	

VI: Medical Devices Quality Management Systems Program

Base program:	Medical Devices Quality Management Systems
Additional accreditation standards	IAF MD9
Certification standards:	ISO 13485:2016



Locations:	A, B, C, D	
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 • IVD medical devices other than specified above
	Sterilization Method for Medical Devices	<ul style="list-style-type: none"> • 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	<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



	Parts and Services	<ul style="list-style-type: none">• Raw materials• Components• Subassemblies• Calibration services• Distribution services• Maintenance services• Transportation services• Other services
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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
Date: 2019-03-15