



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: TÜV SÜD America Inc. Management Service Division

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LOCATION A

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SCC File Number:	08023
Accreditation Standards:	ISO/IEC 17021:2011 IAF MD1, MD2, MD4, MD5, MD11
Initial Accreditation Date:	2001-08-03
Reaccreditation Date:	2015-12-18
Accreditation Expiry Date:	2017-06-15

Additional Critical/Key Locations:

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, CA 92121	San Diego



Location	Country	Address	City
D	USA	TÜV SÜD America Inc. 1775 Old Highway 8 NW New Brighton, MN 55112	New Brighton

I: Quality Management Systems Program

Base program:	Quality Management Systems (QMS)	
Additional accreditation standards	ISO/IEC TS 17021-3:2013 IAF MD3	
Certification standard:	ISO 9001:2008	
Industry sector program(s):		
Locations:	A-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 Excluding sub-NACE DC 19.3 9 Printing Companies Limited to sub-NACE DE 22.2 12 Chemicals, Chemical Products and Fibres 13 Pharmaceuticals 14 Rubber and Plastic Products 15 Non-Metallic Mineral Products Excluding sub-NACE DI 26.1 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 Limited to sub-NACE K 74.2 35 Other Services Limited to sub-NACE K 74.14/74.30/74.80/74.82/74.83/74.84 38 Health and Social Work	



II: Medical Devices Quality Management Systems Program

Base program:	Medical Devices Quality Management Systems	
Additional accreditation standards	GD207; GD210; GD211; Q90R0 IAF MD9	
Certification standards:	ISO 13485:2003 under CMDCAS and ISO 13485:2016 under CMDCAS ISO 13485:2003 and ISO 13485:2016	
Locations:	A-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/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	<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	<ul style="list-style-type: none"> • Medical devices incorporating medicinal



	incorporating/utilizing specific substances/technologies	substances <ul style="list-style-type: none">• 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
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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. Management Service Division. The original version is available in the Directory of Accredited Management Systems Certification Bodies on the SCC website at www.scc.ca.

Chantal Guay, ing., P.Eng.
Vice President, Accreditation Services Date:
2017-03-21