Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: **TUV Rheinland of North America, Inc.**

Contact Name: Balazs Bozsik
CMDCAS Program Manager

LOCATION A

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Operating out of: 1279 Quarry Lane, Suite A
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Location A

SCC File Number:	08027
Accreditation Standards:	ISO/IEC 17021:2011 IAF MD1, MD2, MD4, MD5
Initial Accreditation Date:	2003-03-20
Reaccreditation Date:	2015-08-20
Accreditation Expiry Date:	2019-03-20

Additional Critical/Key Locations:

Location	Country	Address	City
B	Germany	*TÜV Rheinland LGA Products GmbH* *Am Grauen Stein 29* *51105 Köln* *Germany*	Köln
C	Japan	*TUV Rheinland Japan Ltd.* *Global Technology Assessment Center (GTAC)* *4-25-2 Kita-Yamata, Tsuzuki-ku* *Kanagawa-ken* *Yokohama 224-0021*	Yokohama

Location	Country	Address	City
		Japan	
D	China	*TUV Rheinland (Shanghai) Co., Ltd.* *10th Floor, Huatsing Building, No. 88 Lane 777, West Guangzhong Rd.* *Shanghai 200072* *P.R. China*	Shanghai

I: 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 ISO 13485:2003	
Locations:	A, B, C, D	
Certification Body's main technical areas: (IAF MD 8 & MD 9)	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

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to TUV Rheinland of North America, Inc.. 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: 2017-03-01