

Standards Council of Canada Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

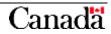
Scope of Accreditation

Accredited Legal Entity:	TUV Rheinland of North America, Inc.
Contact Name:	Balazs Bozsik CMDCAS Program Manager
LOCATION A	
Address:	12 Commerce Rd, Newtown, CT 06470
Telephone:	+1 949 336 1138 ext. 2131
Website:	http://www.us.tuv.com
Email:	bbozsik@us.tuv.com
Operating out of:	1279 Quarry Lane, Suite A Pleasanton, CA 94566
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
В	Germany	TÜV Rheinland LGA Products GmbH Am Grauen Stein 29 51105 Köln Germany	Köln
С	Japan	TUV Rheinland Japan Ltd. Global Technology Assessment Center (GTAC) 4-25-2 Kita-Yamata, Tsuzuki-ku Kanagawa-ken Yokohama 224-0021	Yokohama



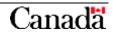


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Location	Country	Address	City
		Japan	
D	China	TUV Rheinland (Shanghai) Co., Ltd. 10th Floor, Huatsing Building, No. 88 Lane 777, West Guangzhong Rd. Shanghai 200072 P.R. China	Shanghai

I: Medical Devices Quality Management Systems Program

Base program:	Medical Devices Quality Management Systems	
Additional accreditatio n 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





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	 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

