Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: **QMI-SAI Canada Limited**

Contact Name: Ginni Sidhu
Interim Head of Technical Services, North America

LOCATION A

Address: 200 - 20 Carlson Court
Toronto, ON M9W 7K6

Telephone: +1 416 401 8725

Fax: +1 416 401 8650

Website: www.qmi-saiglobal.com

Email: ginni.sidhu@saiglobal.com

SCC File Number:	08001
Accreditation Standards:	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD5 (where applicable)
Initial Accreditation Date:	2008-09-10
Reaccreditation Date:	2017-02-02
Accreditation Expiry Date:	2020-09-10

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	Denmark	*Presafe Denmark A/S* *Tuborg Parkvej 8* *Hellerup DK2900 Denmark*	Hellerup
C	Norway	*DNV GL* *Veritasveien 1* *Høvik 1363 Norway*	Høvik
D	Taiwan	*DNV GL Business Assurance*	Taipei

Location	Country	Address	City
		29Fl., No.293, Sec.2, Wenhua Road 220 Ban Chiau Dist., New Taipei City Taiwan	

I: Sustainable Forest Management Program (SFMP)

Base program:	Sustainable Forest Management Program	
Certification standard(s):		CAN/CSA Z809-08 (R2013) CAN/CSA Z809-16
Locations:	A	A
Certification Body's technical scope of accreditation to certify organizations by IAF/NACE codes:	1 Agriculture, Forestry and Fishing	

II: 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	• 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 QMI-SAI Canada Limited. 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: 2019-02-25