Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: **SAI Global Certification Services Pty Ltd.**

Contact Name: Liliana Niculae, P.Eng
Vice President, Business Excellence
Assurance Services (Americas)

LOCATION A

Address: 680 George Street
Level 37-38
Sydney NSW 2000
Australia
+61 2 82066970
www.saiglobal.com

Telephone: +1 416 401 8725

Toll Free: +1 800 465 3717

Fax: +1 416 401 8650

Website: www.qmi-saiglobal.com

Email: Liliana.niculae@saiglobal.com

Operating out of: Location B

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 Critical/Key Locations:

Location	Country	Address	City
B	Canada	*QMI-SAI Canada Limited* *20 Carlson Court, Suite 200* *Toronto, ON M9W 7K6*	Toronto

Canada

Standards Council of Canada
Conseil canadien des normes

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 ISO 9001:2015 CAN3-Z299	
Industry sector program(s):		
Locations:	A, B	A, B
Certification Body's technical scope of accreditation to certify organizations by IAF/NACE codes:	1 Agriculture, Forestry and Fishing • limited to A02.0 2 Mining and Quarrying 3 Food Products, Beverages and Tobacco 4 Textiles and Textile Products 5 Leather and Leather Products 6 Wood and Wood Products 7 Pulp, Paper and Paper Products 8 Publishing Companies 9 Printing Companies 10 Manufacture of Coke and Refined Petroleum Products 12 Chemicals, Chemical Products and Fibres 13 Pharmaceuticals 14 Rubber and Plastic Products 15 Non-Metallic Mineral Products 16 Concrete, Cement, Lime, Plaster, etc. 17 Basic Metals and Fabricated Metal Products 18 Machinery and Equipment 19 Electrical and Optical Equipment 20 Shipbuilding 21 Aerospace 22 Other Transport Equipment 23 Manufacturing Not Elsewhere Classified 25 Electricity Supply 26 Gas Supply 27 Water Supply 28 Construction 29 Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 30 Hotels and Restaurants 31 Transport, Storage and Communication 32 Financial Intermediation; Real Estate; Renting 33 Information Technology 34 Engineering Services	

Canada

35	Other Services	
36	Public Administration	
37	Education	
38	Health and Social Work	
39	Other Social Services	

II: Environmental Management Systems Program

Base program:	Environmental Management Systems (EMS)	
Additional accreditation standards	ISO/IEC TS 17021-2:2013 IAF MD3	
Certification standard(s):	ISO 14001:2004 ISO 14001:2015	CAN/CSA Z804:2008 (R2013) CAN/CSA Z809:2008 (R2013)
Industry sector program(s):		Sustainable Forest Management Program (SFMP)
Locations:	A, B	A, B
Certification Body's technical scope of accreditation to certify organizations by IAF/NACE codes:	1 Agriculture, Forestry and Fishing 2 Mining and Quarrying 3 Food Products, Beverages and Tobacco 4 Textiles and Textile Products 5 Leather and Leather Products 6 Wood and Wood Products 7 Pulp, Paper and Paper Products 8 Publishing Companies 9 Printing Companies 10 Manufacture of Coke and Refined Petroleum Products 11 Nuclear fuel 12 Chemicals, Chemical Products and Fibres 13 Pharmaceuticals 14 Rubber and Plastic Products 15 Non-Metallic Mineral Products 16 Concrete, Cement, Lime, Plaster, etc. 17 Basic Metals and Fabricated Metal Products 18 Machinery and Equipment 19 Electrical and Optical Equipment 20 Shipbuilding 21 Aerospace	

| | 22 Other Transport Equipment
23 Manufacturing Not Elsewhere Classified
24 Recycling
25 Electricity Supply
26 Gas Supply
27 Water Supply
28 Construction
29 Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods
30 Hotels and Restaurants
31 Transport, Storage and Communication
32 Financial Intermediation; Real Estate; Renting
33 Information Technology
34 Engineering Services
35 Other Services
36 Public Administration
37 Education
38 Health and Social Work
39 Other Social Services | |

III: 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:	B	
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

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to SAI Global Certification Services Pty Ltd. 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: 2017-05-03

Canada