



**MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)**

**Scope of Accreditation**

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

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**LOCATION A**

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<b>SCC File Number:</b>	08001
<b>Accreditation Standards:</b>	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD5 (where applicable)
<b>Initial Accreditation:</b>	2008-09-10
<b>Most Recent Accreditation:</b>	2020-07-28
<b>Accreditation Valid to:</b>	2021-03-10

**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	<i>Presafe Denmark A/S Tuborg Parkvej 8 Hellerup DK2900 Denmark</i>	Hellerup
C	Norway	<i>DNV GL Veritasveien 1 Høvik 1363 Norway</i>	Høvik
D	Taiwan	<i>DNV GL Business Assurance 29Fl., No.293, Sec.2, Wenhua Road 220 Ban Chiau Dist., New Taipei City Taiwan</i>	Taipei



**I: Sustainable Forest Management Program (SFMP)**

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

**II: Medical Device Management Systems Program**

<b>Base program:</b>	Medical Device Management Systems (MDMS)	
<b>Additional accreditation standards</b>	IAF MD 9:2017	
<b>Certification standards:</b>	ISO 13485:2016	
<b>Locations:</b>	A, B, C, D	
<b>Certification Body's main technical areas:</b>	Non-active Medical Devices	<ul style="list-style-type: none"> <li>• General non-active, non-implantable medical devices</li> <li>• Non-active implants</li> <li>• Devices for wound care</li> <li>• Non-active dental devices and accessories</li> <li>• Non-active medical devices other than specified above</li> </ul>
	Active Medical Devices (Non-Implantable)	<ul style="list-style-type: none"> <li>• General active medical devices</li> <li>• Devices for imaging</li> <li>• Monitoring devices</li> <li>• Devices for radiation therapy and thermo therapy</li> <li>• Active (non-implantable) medical devices other than specified above</li> </ul>
	Active Implantable Medical Devices	<ul style="list-style-type: none"> <li>• General active implantable medical devices</li> <li>• implantable medical devices other than specified above</li> </ul>
	In Vitro Diagnostic Medical Devices (IVD)	<ul style="list-style-type: none"> <li>• Reagents and reagent products, calibrators and control materials for:               <ul style="list-style-type: none"> <li>– Clinical Chemistry</li> </ul> </li> </ul>



		<ul style="list-style-type: none"> <li>- Immunochemistry (Immunology)</li> <li>- Haematology/Haemostasis/Immunoematology</li> <li>- Microbiology</li> <li>- Infectious Immunology</li> <li>- Histology/Cytology</li> <li>- Genetic Testing</li> <li>• In Vitro Diagnostic Instruments and software</li> <li>• IVD medical devices other than specified above</li> </ul>
	Sterilization Method for Medical Devices	<ul style="list-style-type: none"> <li>• Ethylene oxide gas sterilization (EOG)</li> <li>• Moist heat</li> <li>• Aseptic processing</li> <li>• Radiation sterilization (e.g. gamma, x-ray, electron beam)</li> <li>• Sterilization method other than specified above</li> </ul>
	Devices incorporating/utilizing specific substances/technologies	<ul style="list-style-type: none"> <li>• Medical devices incorporating medicinal substances</li> <li>• Medical devices utilizing tissues of animal origin</li> <li>• Medical devices incorporating derivatives of human blood</li> <li>• Medical devices utilizing micromechanics</li> <li>• Medical devices utilizing nanomaterials</li> <li>• Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed</li> <li>• Medical devices incorporating or utilizing specific substances/technologies/ elements, other than specified above</li> </ul>

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](http://www.scc.ca).

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Elias Rafoul  
 Vice-President, Accreditation Services  
 Publication on: 2020-09-17