

## MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

### Scope of Accreditation

*La présente portée d'accréditation existe également en français et est publiée séparément.*

**Accredited Legal Entity:** National Standards Authority of Ireland (NSAI)

Contact Name: Ms. Pamela Burdette Miller  
U.S. Medical Operations Manager

#### LOCATION A

Address: 1 Swift Square  
Northwood, Santry, Dublin 9  
Ireland D09 A0E4

Telephone: +353 1 807 3800  
Fax: +353 1 807 3838

Website: [www.nsai.ie](http://www.nsai.ie)

Email: [Pamela.BurdetteMiller@NSAIInc.com](mailto:Pamela.BurdetteMiller@NSAIInc.com)

<b>SCC File Number:</b>	08028
<b>Accreditation Standards:</b>	ISO/IEC 17021-1:2015 IAF MD 1:2023, MD 2:2023, MD 4:2023, MD 5:2023
<b>Initial Accreditation:</b>	2003-12-31
<b>Most Recent Accreditation:</b>	2024-03-06
<b>Accreditation Valid to:</b>	2027-12-31

#### 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	USA	NSAI Inc. 20 Trafalgar Square, Suite 603 Nashua NH 03063 USA	Nashua

## I: Quality Management Systems Program

<b>Base program:</b>	Quality Management Systems (QMS)	
<b>Additional accreditation standards</b>	ISO/IEC 17021-3:2017 IAF MD 5:2023	
<b>Certification standard:</b>	ISO 9001:2015	
<b>Locations:</b>	A, B	
<b>Certification Body's technical scope of accreditation to certify organizations by IAF codes:</b>	12	Chemicals, Chemical Products and Fibres
	14	Rubber and Plastic Products
	17	Basic Metals and Fabricated Metal Products
	18	Machinery and Equipment
	19	Electrical and Optical Equipment
	23	Manufacturing Not Elsewhere Classified
	33	Information Technology

## II: Medical Device Management Systems Program

<b>Base program:</b>	Medical Device Management Systems (MDMS)	
<b>Additional accreditation standards</b>	IAF MD 9:2023	
<b>Certification standards:</b>	ISO 13485:2016	
<b>Locations:</b>	A, B	
<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>
	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> </ul>
	Parts and Services	<ul style="list-style-type: none"> <li>• Raw materials</li> <li>• Components</li> <li>• Subassemblies</li> <li>• Maintenance services</li> </ul>



This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to National Standards Authority of Ireland (NSAI). 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).

---

Elias Rafoul  
Vice-President, Accreditation Services  
Publication on: 2024-07-10