MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

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

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LOCATION A

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SCC File Number:	08028
Accreditation Standards:	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD4, MD5 (where applicable)
Initial Accreditation:	2003-12-31
Most Recent Accreditation:	2022-09-14
Accreditation Valid to:	2023-12-31

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

Base program:	Quality Management Systems (QMS)
Additional accreditation standards	ISO/IEC 17021-3:2017 IAF MD 5
Certification standard:	ISO 9001:2015
Locations:	A, B
Certification Body's technical scope of accreditation to certify organizations by IAF codes:	12 Chemicals, Chemical Products and Fibres 13 Pharmaceuticals 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

Base program:	Medical Device Management Systems (MDMS)	
Additional accreditation standards	IAF MD 9:2017	
Certification standards:	ISO 13485:2016	
Locations:	A, B	
Certification Body's main technical areas:	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
	In Vitro Diagnostic Medical Devices (IVD)	• Reagents and reagent products, calibrators and control materials for: – Clinical Chemistry – Immunochemistry (Immunology) – Haematology/Haemostasis/Immuno hematology – 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
	Parts and Services	• Raw materials • Components • Subassemblies • Maintenance services

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.

Elias Rafoul
Vice-President, Accreditation Services
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