SCC

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: **Intertek Testing Services NA Ltd. trading as Intertek**

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LOCATION A

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Operating out of: (Location B) 4700 Broadmoor SE, Suite 200
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SCC File Number:	08006
Accreditation Standards:	ISO/IEC 17021-1:2015 IAF MD 1:2018, MD 2:2017, MD 4:2018
Initial Accreditation:	1993-02-02
Most Recent Accreditation:	2022-02-04
Accreditation Valid to:	2023-08-02

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	United States of America	Intertek 4700 Broadmoor SE, Suite 200 Kentwood, MI 49512 USA	Kentwood

Canada

I: Medical Device Management Systems Program

Base program:	Medical Device Management Systems (MDMS)	
Additional accreditation standards	IAF MD 9:2022	
Certification standards:	ISO 13485:2016	
Locations:	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
	Active Medical Devices (Non-Implantable)	• General active medical devices • Devices for imaging • Monitoring devices • Devices for radiation therapy and thermo therapy
	~~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 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
	Parts and Services	• Components • Subassemblies • Calibration services • Distribution services • Maintenance services • Transportation services • Other services

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to Intertek Testing Services NA Ltd. trading as Intertek. 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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