



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: Intertek Testing Services NA Inc.
trading as Intertek and Intertek SAI Global

Contact Name: Nitin Shahani
Technical Director, Business Assurance NA

LOCATION A

Address: 4700 Broadmoor SE Suite 200
Kentwood, MI 49512 United States

Telephone: +1 905 691 5193

Fax: +1 616 656 2022

Website: www.intertek.com

Email: nitin.shahani@intertek.com

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:	2024-03-28
Accreditation Valid to:	2027-02-02

Additional Fixed Office Locations (FOL):

See the address of the above legal entity. No other location is included in the accreditation.

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:	A

Certification Body's main technical areas:	Non-active Medical Devices	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • General active medical devices • Devices for imaging • Monitoring devices • Devices for radiation therapy and thermos therapy
	In Vitro Diagnostic Medical Devices (IVD)	<ul style="list-style-type: none"> • Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> – Clinical Chemistry – Immunochemistry (Immunology) – Haematology/Haemostasis/Immunoematology – 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Components • Subassemblies • Calibration services • Distribution services • Maintenance services



	<ul style="list-style-type: none">• 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 Inc. 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
Publication on: 2024-03-28