Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: BSI Group America Inc. (also operating under BSI Inc.)

Contact Name: Angie Combs
Technical Manager, Medical Devices

LOCATION A

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SCC File Number:	08024
Accreditation Standards:	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD5, (where applicable)
Initial Accreditation Date:	2002-12-11
Reaccreditation Date:	2016-09-07
Accreditation Expiry Date:	2020-12-11

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
A	United Kingdom	*BSI Group* *Kitemark Court, Davy Avenue,* *Knowlhill, Milton Keynes MK5 8PP* *UK*	Milton Keynes

Canada

I: Medical Devices Quality Management Systems Program

Base program:	Medical Devices Quality Management Systems	
Additional accreditation standards	IAF MD9	
Certification standards:	ISO 13485:2016	
Locations:	A	
Certification Body's main technical areas: (IAF MD 8 & MD 9)	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 • 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 incorporating derivatives of human blood

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to BSI Group America Inc. (also operating under BSI 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
Date: 2019-06-28