

## MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

## **Scope of Accreditation**

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

Contact Name: Carlos Pitanga

SVP, System Certification Operations & Compliance

**LOCATION A** 

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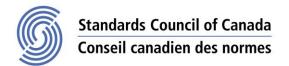
Email: Carlos.Pitanga@bsigroup.com

SCC File Number:	08024
Accreditation Standards: ISO/IEC 17021:2011 IAF MD1, MD2, MD5, (where applicable)	
Initial Accreditation Date:	2002-12-11
Reaccreditation Date:	2016-09-07
Accreditation Expiry Date:	2020-12-11

## **Additional Critical/Key Locations:**

Location	Country	Address	City
В	Brazil	BSI Brazil Rua Gomes de Carvalho 1069, - 18 Andar, Vila Olimpia, 04547-004 Sao Paulo / SP Brazil	Sao Paulo
С	China	BSI MS Certification – (Beijing) Co Ltd Room 2008 East Ocean Center, 24A Jianguomenwai Street, Beijing China	Beijing
D	India	BSI India Pvt Ltd	New Delhi





Location	Country	Address	City
		The MIRA Corporate Suites (A-2), Plot 1 7 2 Ishwar Nagar, Mathura Road, New Delhi India	
E	Japan	BSI Japan K.K. Seizan Bldg. 5F, 2-12-28 Kita- Aoyama Mitato-ku. Tokyo Japan 107-0061	Tokyo
F	Mexico	BSI Group Mexico S. de R.L. de C.V. Torre Mayor Av. Paseo de La Reforma No. 505 – 41C, Mexico City Mexico	Mexico City
G	Singapore	BSI Group Singapore Pte Ltd. 3 Lim Teck Kim Rd, #10-02 Genting Centre, 088934 Singapore	Singapore
Н	Korea	BSI Korea Ltd. 21F, Jongo Tower Bldg, #6 Jongo 2-ga Seoul, 110-789 KOREA	Seoul
I	United Kingdom	BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP UK	Milton Keynes
J	Canada	BSI Group Canada Inc. 6205 B Airport Road, Suite 414, Mississauga, ON L4V 1E1 Canada	Mississauga

## I: Medical Devices Quality Management Systems Program

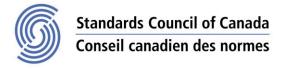
Base program:	Medical Devices Quality Management Systems	
Additional accreditation standards	GD207; GD210; GD211; Q90R0 (for CMDCAS only) IAF MD9 (for non-CMDCAS)	
Certification standards:	ISO 13485:2016 under CMDCAS ISO 13485:2003 under CMDCAS ISO 13485:2016 ISO 13485:2003	
Locations:	A, B, C, D, E, F, G, H, I, J	
Certification Body's main technical areas:	Non-active Medical Devices	<ul> <li>General non-active, non-implantable medical devices</li> <li>Non-active implants</li> <li>Devices for wound care</li> </ul>





(IAF MD 8 & MD 9)		<ul> <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> <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>
	Active Implantable Medical Devices	<ul> <li>General active implantable medical devices</li> <li>implantable medical devices other than specified above</li> </ul>
	In Vitro Diagnostic Medical Devices (IVD)	<ul> <li>Reagents and reagent products, calibrators and control materials for:         <ul> <li>Clinical Chemistry</li> <li>Immunochemistry (Immunology)</li> <li>Haematology/Haemostasis/Immunohematolog y</li> <li>Microbiology</li> <li>Infectious Immunology</li> <li>Histology/Cytology</li> <li>Genetic Testing</li> </ul> </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> <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> <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> </ul>





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.

Chantal Guay, ing., P.Eng. Vice President, Accreditation Services

Date: 2016-11-18