



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

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

Contact Name: Carlos Pitanga
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LOCATION A

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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
B	Brazil	<i>BSI Brazil Rua Gomes de Carvalho 1069, - 18 Andar, Vila Olimpia, 04547-004 Sao Paulo / SP Brazil</i>	Sao Paulo
C	China	<i>BSI MS Certification – (Beijing) Co Ltd Room 2008 East Ocean Center, 24A Jianguomenwai Street, Beijing China</i>	Beijing
D	India	<i>BSI India Pvt Ltd</i>	New Delhi



Location	Country	Address	City
		<i>The MIRA Corporate Suites (A-2), Plot 1 7 2 Ishwar Nagar, Mathura Road, New Delhi India</i>	
E	Japan	<i>BSI Japan K.K. Seizan Bldg. 5F, 2-12-28 Kita-Aoyama Mitato-ku. Tokyo Japan 107-0061</i>	Tokyo
F	Mexico	<i>BSI Group Mexico S. de R.L. de C.V. Torre Mayor Av. Paseo de La Reforma No. 505 – 41C, Mexico City Mexico</i>	Mexico City
G	Singapore	<i>BSI Group Singapore Pte Ltd. 3 Lim Teck Kim Rd, #10-02 Genting Centre, 088934 Singapore</i>	Singapore
H	Korea	<i>BSI Korea Ltd. 21F, Jongo Tower Bldg, #6 Jongo 2-ga Seoul, 110-789 KOREA</i>	Seoul
I	United Kingdom	<i>BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP UK</i>	Milton Keynes
J	Canada	<i>BSI Group Canada Inc. 6205 B Airport Road, Suite 414, Mississauga, ON L4V 1E1 Canada</i>	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 style="list-style-type: none"> • General non-active, non-implantable medical devices • Non-active implants • Devices for wound care



(IAF MD 8 & MD 9)		<ul style="list-style-type: none"> • Non-active dental devices and accessories • Non-active medical devices other than specified above
	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 thermo therapy • Active (non-implantable) medical devices other than specified above
	Active Implantable Medical Devices	<ul style="list-style-type: none"> • General active implantable medical devices • implantable medical devices other than specified above
	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/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	<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 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.

Chantal Guay, ing., P.Eng.
Vice President, Accreditation Services
Date: 2016-11-18