



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

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

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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: | 2002-12-11 |
| Most Recent Accreditation: | 2020-05-09 |
| Accreditation Valid to: | 2024-06-12 |

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 Kingdom | <i>BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP UK</i> | Milton Keynes |



I: Medical Devices Quality Management Systems Program

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| 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 | <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 • 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/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 | <ul style="list-style-type: none"> • Ethylene oxide gas sterilization (EOG) • Moist heat • Aseptic processing |



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| | | <ul style="list-style-type: none">• 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• 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 or elements, other than specified above |
| | Parts and Services | <ul style="list-style-type: none">• Raw materials• 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 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
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