

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan
Utah
84095
USA

Facility ID Number: F000304

Holds Certificate No:

MDSAP 678257

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-04-20

Effective Date: 2022-02-23

Expiry Date: 2023-12-20



BSI Group America Inc. is an MDSAP authorized auditing organization

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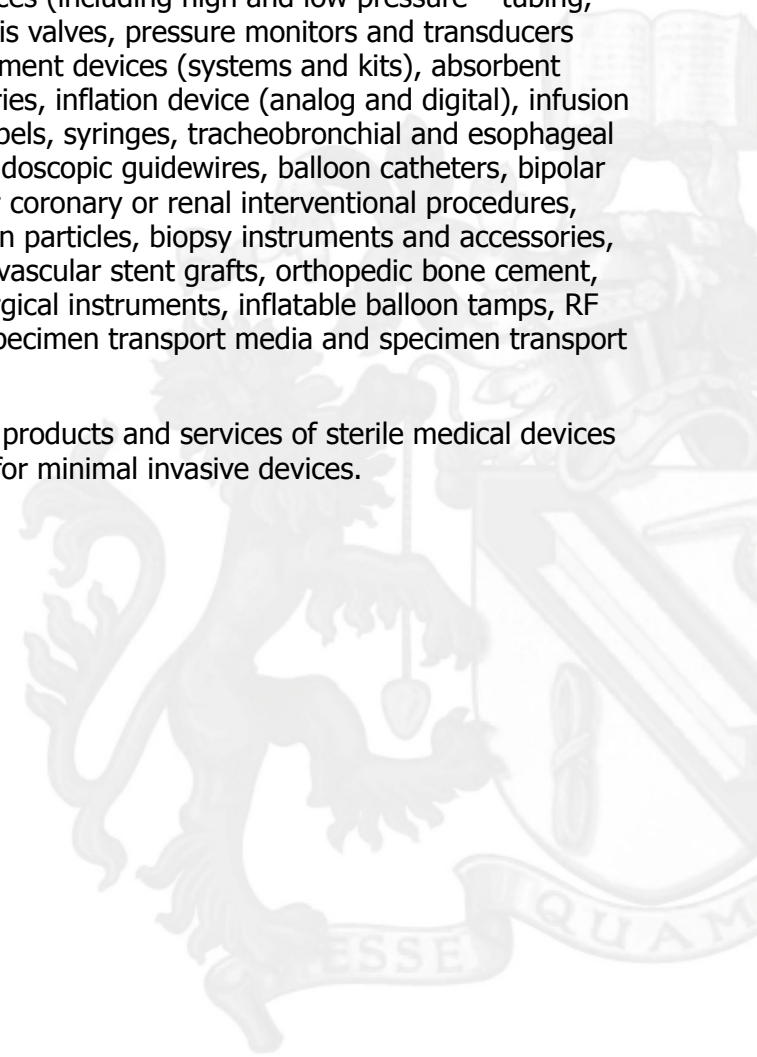
...making excellence a habit.™

Certificate No: **MDSAP 678257**

Registered Scope:

The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) including angiographic, angioplasty and other procedure kits/packs, angiographic catheters, vascular catheters, peripheral catheters, guiding catheters, guidewires (coated and uncoated), occluding guidewires, guidewire insertion tools, introducer needles, trocars, hemodialysis catheters, obturators, sharps holders, kits, introducer devices, insertion devices, torque devices, waste disposal systems, flush devices, fluid administration/handling devices (including high and low pressure – tubing, manifolds, stopcocks, valves) and kits, dilators, hemostasis valves, pressure monitors and transducers (including electronic), drainage devices, contrast management devices (systems and kits), absorbent swabs, embolectomy devices, snare devices and accessories, inflation device (analog and digital), infusion devices, angiographic needles, compression devices, scalpels, syringes, tracheobronchial and esophageal stent systems (and accessories), biliary stent systems, endoscopic guidewires, balloon catheters, bipolar coagulation probes, stent positioning system intended for coronary or renal interventional procedures, peritoneal dialysis catheters, accessories kits, embolization particles, biopsy instruments and accessories, vascular grafts and graft accessory component kits, endovascular stent grafts, orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments, inflatable balloon tamps, RF tumor ablation systems for orthopedic applications and specimen transport media and specimen transport collection kits.

Design, Development and Manufacture under contract of products and services of sterile medical devices and associated accessories, and non-sterile components for minimal invasive devices.



Original Registration Date: 2018-04-20

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
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Certificate No: **MDSAP 678257**

Location

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1600 West Merit Parkway
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84095
USA
Facility ID Number: F000304

Registered Activities

The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) including angiographic, angioplasty and other procedure kits/packs, angiographic catheters, vascular catheters, peripheral catheters, guiding catheters, guidewires (coated and uncoated), introducer needles, angiographic needles, trocars, hemodialysis catheters, introducer devices, dilators, transducers, drainage devices, contrast management devices, compression devices, absorbent swabs, embolectomy devices, inflation systems (analog and digital), scalpels, torque devices, tubing, manifolds/stopcocks, valves, syringes, waste disposal, tracheobronchial and esophageal stent systems (and accessories), biliary stent systems, balloon catheters, bipolar coagulation probes and all related accessories, stent positioning system intended for coronary or renal interventional procedures, peritoneal dialysis catheters, accessories and kits, embolization particles, biopsy instruments and accessories, vascular grafts and graft accessory component kits, endovascular stent grafts, and orthopedic surgical instruments, inflatable balloon tamps, RF tumor ablation systems for orthopedic applications and specimen transport media and specimen transport collection kits.

Design, Development and Manufacture under contract of products and services of sterile medical devices and associated accessories, and non-sterile components for minimal invasive devices.

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Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 678257**

Location	Registered Activities
Merit Medical Ireland Ltd Parkmore Business Park West Galway Ireland Facility ID Number: F001907	<p>The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) for infusion, drainage angiography needles, analog inflation devices, occluding guidewires, guide wires (coated and uncoated), tubing, stopcocks, manifolds (including high pressure), angioplasty procedure packs containing guidewire insertion tools, hemostasis valves and torque devices, disposal depots, disposal pressure transducers, fluid administration and contrast management sets (with or without adaptors), insertion devices, torque devices, introducer needles, angiographic needles, obturators, temporary sharps holders, waste disposal basins, fluid administration, scalpels, flush devices, endovascular snare devices and accessories, peripheral catheters, orthopedic bone cement, bone cement delivery devices/accessories, biopsy Instruments and accessories, inflatable balloon tamps and RF tumor ablation systems for orthopedic applications.</p> <p>Design, Development and Manufacture under contract of products and services of sterile medical devices and associated accessories, and non-sterile components for minimal invasive devices.</p>
Merit Medical Systems, Inc. 14646 Kirby Drive Houston Texas 77047 USA Facility ID Number: F001909	<p>Design, development, manufacture, packaging, and distribution of sterile medical devices including catheters and guide catheters (braided and non-braided), (single and multipack), introducers (vascular and non-vascular), dilators (vascular and non-vascular), tracheobronchial and esophageal stent systems (and accessories), biliary stent systems and associated kits (single and multipack) for angiography, drainage, coronary and peripheral applications.</p> <p>Design, Development and Manufacture under contract of products and services of sterile medical devices and associated accessories, and non-sterile components for minimal invasive devices.</p>

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Location

Merit Maquiladora México,
S. DE R.L. DE C.V.
Avenida Sor Juana Inés de la Cruz
19970 interior B, Edificio 2
Parque Industrial Frontera
Tijuana, Baja California
Baja California
C.P. 22630
Mexico
Facility ID Number: F001906

Registered Activities

The design, development, manufacture and packaging of sterile medical devices including Infusion Devices, Catheters, Guide Catheters and associated kits (single & multipack) for angiography, drainage, coronary and peripheral applications, fixation devices, Vascular & Non-Vascular, Introducers and Dilators, Scalpels, Biopsy Instruments and Accessories, Waste Disposal Systems, Sharps Holders, Fluid Administration/Handling Devices (Including High and Low Pressure – Tubing, Manifolds, Compression Devices, Contrast Management Devices (Systems and Kits)), absorbent swabs, hemostasis valves, analog inflation devices, angioplasty procedure packs containing guidewire insertion tools, hemostasis valves and torque devices, and associated kits.

Design, Development and Manufacture under contract of products and services of sterile medical devices and associated accessories, and non-sterile components for minimal invasive devices.



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