By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

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

Holds Certificate No: **FM 534441**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Please see scope page.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2008-09-05 Effective Date: 2017-12-21 Expiry Date: 2018-12-31

CMDCAS Recognized Registrar

SCC Accredited CB-MS OCSM Accrédité CCN

...making excellence a habit.™

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
To be read in conjunction with the scope above or the attached appendix.

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: **FM 534441**

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, trocars, introducer needles, 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), 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, orthopedic bone cement, bone cement delivery devices/accessories, inflatable balloon tamps, orthopedic surgical instruments and RF tumor ablation systems for orthopedic applications and non-sterile customer specified components for minimally invasive medical devices.

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Certificate No: **FM 534441**

Location	Registered Activities
Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan Utah 84095 USA	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), vascular trocars, hemodialysis catheters, , introducer devices, dilators, transducers, drainage devices, contrast management devices, embolectomy devices, snare 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, 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, and orthopedic surgical instruments and RF tumor ablation systems for orthopedic applications.
Merit Medical Ireland Ltd Parkmore Business Park West Galway Ireland	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, orthopedic bone cement, bone cement delivery devices/accessories, inflatable balloon tamps and RF tumor ablation systems for orthopedic applications and non-sterile customer specified components for minimally invasive medical devices.
Merit Medical Systems, Inc. 1375 West 8040 South West Jordan Utah 84088 USA	The manufacture of medical devices including drainage catheter sets, vascular and non-vascular introducers, vascular and non-vascular dilators and kits.

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Location	Registered Activities
Merit Holdings, Inc. Amerikalaan 42 6199 AE Maastricht-Airport The Netherlands	Customer service, labeling and distribution.
Merit Medical Systems, Inc. 14646 Kirby Drive Houston Texas 77047 USA	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.
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 C.P. 22630 Mexico	The manufacture, packaging and distribution of sterile medical devices including Infusion Devices, Catheters and Guide Catheters, fixation devices -, Vascular & Non-Vascular, Introducers and Dilators, Scalpels, Waste Disposal Systems, Sharps Holders, Fluid Administration/Handling Devices (Including High and Low Pressure - Tubing, Manifolds, - Compression Devices and Contrast Management Devices (Systems and Kits).

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