

# 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:



VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 09/05/2008

Effective Date: 12/22/2014

Expiry Date: 12/21/2017



CMDCAS  
Recognized  
Registrar



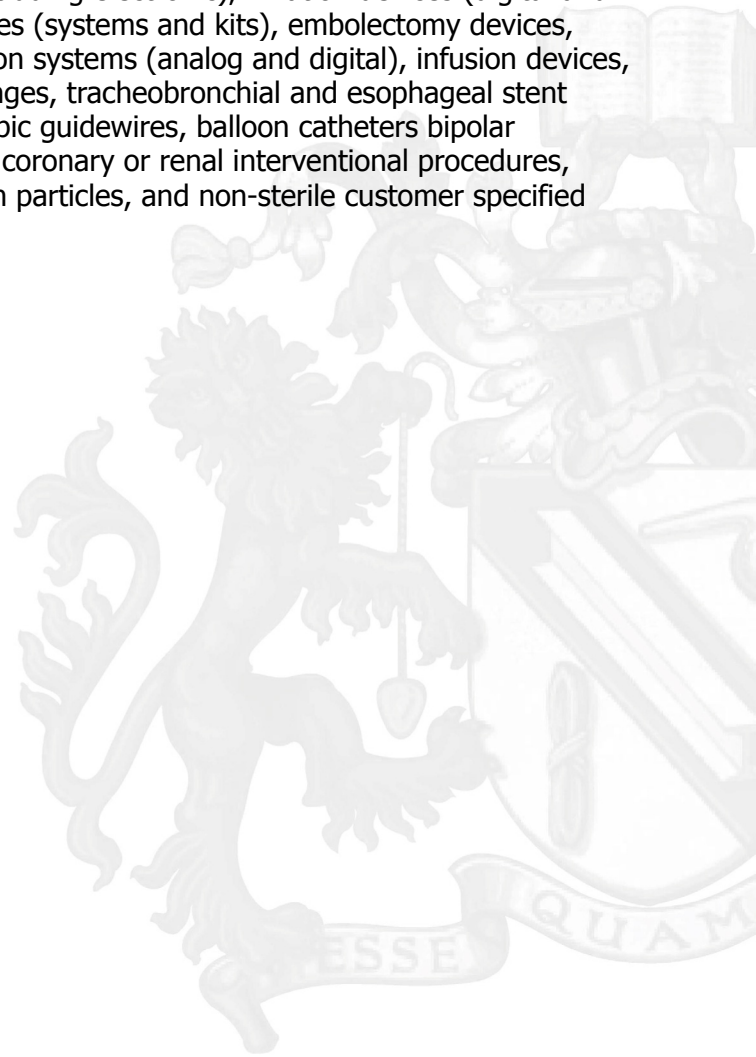
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...making excellence a habit.™

Certificate No: **FM 534441**

## Registered Scope:

The design, development, manufacture and distribution of 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, hemodialysis catheters, obturators sharps holders, 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), inflation devices (digital and electronic), drainage devices, contrast management devices (systems and kits), embolectomy devices, snare devices and accessories, hemostasis devices, inflation systems (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, and non-sterile customer specified components for minimally invasive medical devices.



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This certificate remains the property of BSI and shall be returned immediately upon request.  
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To be read in conjunction with the scope above or the attached appendix.

Certificate No: **FM 534441**

Location

Registered Activities

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

The design, development, manufacture and distribution of 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, hemodialysis catheters, obturators sharps holders, 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), inflation devices (digital and electronic), drainage devices, contrast management devices (systems and kits), embolectomy devices, snare devices and accessories, hemostasis devices, inflation systems (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, and non-sterile customer specified components for minimally invasive medical devices.

Merit Medical Ireland Ltd  
Parkmore Business Park West  
Galway  
Ireland

Design development, manufacture and distribution of medical devices for infusion, drainage and pressure monitoring (including electronic); angiography needles, analog and digital inflation devices, occluding guide wires, guide wires (coated and uncoated), tubing, stopcocks, manifolds (including high pressure), angioplasty procedure packs containing guide wire insertion tools, hemostasis valves and torque devices, disposal depots, disposable 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, embolization particles, and non-sterile customer specified components for minimally invasive medical devices.

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Location	Registered Activities
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.
Merit Holdings, Inc. Amerikalaan 42 6199 AE Maastricht-Airport Netherlands	Customer service, labeling and distribution.
Merit Medical Systems, Inc. 14646 Kirby Drive Houston Texas 77047 USA	Design, development, manufacture and distribution of medical devices including catheters and guide catheters (braided and non-braided), (single and multipack), introducers (vascular and non-vascular), dilators (vascular and non-vascular) and associated kits (single and multipack) for angiography, drainage, coronary and peripheral applications.

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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.