



# 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:*

The design and development, manufacture and distribution of medical devices for infusion, drainage, angiography and angioplasty, including cardiovascular catheters and pressure monitors (including electronic), embolectomy catheters, tracheobronchial stent systems, esophageal stent systems, endoscopic guidewires, biliary stent systems and bipolar hemostasis probes. Medical devices for infusion, irrigation, angiography and angioplasty as specified in the attachment to this file. Infusion systems, syringes, drainage bags, inflation devices, angiography and angioplasty kits with inflation devices, scalpels and introducers/dilators (vascular and non-vascular), hemodialysis catheters, non-vascular balloon catheters, kits, endovascular snare devices and accessories.

*For and on behalf of BSI:*

*VP Regulatory Affairs, BSI Group America Inc.*

Originally Registered: **09/05/2008**

Effective Date: **01/04/2012**

Expiry Date: **01/03/2015**



**CMDCAS**  
**Recognized**  
**Registrar**



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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](http://www.bsigroup.com/ClientDirectory). To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.  
A Member of the BSI Group of Companies.



Certificate No: **FM 534441**

**Location**

**Registered Activities**

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

The design and development, manufacture and distribution of medical devices for infusion, drainage, angiography and angioplasty, including cardiovascular catheters and pressure monitors (including electronic), embolectomy catheters, tracheobronchial stent systems, esophageal stent systems, endoscopic guidewires, biliary stent systems and bipolar hemostasis probes. Medical devices for infusion, irrigation, angiography and angioplasty as specified in the attachment to this file. Infusion systems, syringes, drainage bags, inflation devices, angiography and angioplasty kits with inflation devices, scalpels and introducers/dilators (vascular and non-vascular), hemodialysis catheters, non-vascular balloon catheters, kits, and accessories.

Merit Medical Systems, Inc.  
Angleton Division  
1111 South Velasco  
Angleton  
Texas  
77515  
USA

Manufacture and distribution of medical devices (braided and non-braided), angiography catheter kits, angiographic catheter multipack, drainage catheters, guide catheters, angiography, vascular and non-vascular introducers, vascular and non-vascular dilators.

Merit Medical Ireland Ltd  
Parkmore Business Park West  
Galway  
Ireland

Design, development, production and distribution of medical devices for infusion, drainage, and pressure monitors (including electronic): angiographic needles, analog inflation syringes, syringes, occluding guide wires, guide wires (coated and uncoated), high pressure stopcocks, high pressure connector tubing, 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 adaptors, manifolds, stopcocks, introducer needles, obturators, temporary sharps holders, waste disposal basins, scalpels, flush devices, endovascular snare devices and accessories.

Originally Registered: **09/05/2008**

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**Location**

**Registered Activities**

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

The design, manufacture and distribution of stent devices, sterile guide-wire applicators, bipolar hemostatic probes, inflation devices, non-vascular balloon catheters, and other products for the clinical treatments of intrinsic or extrinsic luminal disease in the gastrointestinal and pulmonary systems.

Merit Medical Systems, Inc.  
8040 South 1375 West  
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 Medical Systems, Inc.  
79 West 4500 South  
Murray  
Utah  
84107  
USA

The manufacture of medical devices including infusion systems, fluid administration and contrast management sets with adaptors, manifolds, stopcocks, angiography, and introducer needles, temporary sharps holders, waste disposal basins, and kits.

Merit Holdings, Inc.  
Amerikalaan 42  
6199 AE Maastricht-Airport  
Netherlands

Customer service and distribution.

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