

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 541900**

Issued To:

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

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2008-10-03**Date: **2020-11-17**Expiry Date: **2023-10-02****...making excellence a habit.™**

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Certificate No: CE 541900

Certificate Scope:

The design, development and manufacture of sterile angiographic, angioplasty and other procedure kits/packs, angiographic catheters, cardiac catheters, vascular catheters, peripheral catheters, guiding catheters, guide wires (coated and uncoated), vascular trocars, introducer needles, angiographic needles, hemodialysis catheters, introducer devices, dilators, transducers, drainage devices, contrast management devices, embolectomy devices, snare devices, hemostasis devices, balloon inflation systems, scalpels, tubing, manifolds/stopcocks, valves, syringes, tracheobronchial stent systems, esophageal stent systems, stent positioning system intended for coronary or renal interventional procedures, peritoneal dialysis catheters, accessories and kits, embolization particles, biopsy instruments and accessories, vascular grafts, graft accessory component kits, orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments and RF tumor ablation systems for orthopedic applications, percutaneous transluminal angioplasty (PTA) catheters, caps for the disinfection of vascular access connectors, bipolar coagulation probes and all related accessories, rotating tip venous infusion catheters, endovascular stent graft systems.

The design, development and manufacture of non-sterile hemostasis devices, manifolds, and stopcocks.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of angiographic, angioplasty and other procedure kits/packs, anesthesia conduction catheter fixation devices, catheter flush devices, infusion systems, syringes, suture retention devices, torque devices, drainage/waste/sharps collection devices, surgical/general purpose organizers, abdominal binders, labeling sets, compression devices, balloon inflation systems, non-vascular balloon catheter systems, nasopharyngeal swabs, peritoneal dialysis accessories and kits and all related accessories.

Those aspects of Annex II related to metrology in the manufacture of syringes, tracheal measuring devices, balloon inflation systems and all related accessories.

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NBOG code(s)	Device description	Intended purpose
Class III		
MD 0102/MD 0106, MDS7006	Angiographic and Guide Catheters	See CE 538238
MD 0102, MDS7006	Drainage Catheters	See CE 541480
MD 0106, MDS7006	EN Snare Endovascular Snare System EMPOWER Tri-Loop Snare System	See CE 555846
MD 0106, MDS7006	InQwire® Diagnostic Guide Wires, InQwire® Amplatz Guide Wires	See CE 560101
MD 0106, MDS7006	Merit Embolectomy Catheters	See CE 561259
MD 0106, MDS7006	Ostial Pro Stent Positioning System	See CE 585005
MD 0106, MDS7006	ONE Snare Endovascular Snare System, ONE Snare Endovascular Microsnare System EMPOWER Single-Loop Snare System	See CE 590890
MD 0102, MDS7006	Hemodialysis Catheters	See CE 606106
MD 0106, MDS7006	Merit SureCross™ Support Catheter	See CE 612029
MD 0102, MDS7006	HeRO Graft	See CE 650631
MD 0106, MDS7006	SwiftNINJA Steerable Microcatheters	See CE 667696
MD 0106, MDS7006	True Form Reshapable Guide Wire	See CE 669204

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Class IIb		
MD 0204, MDS7006	Drainage Devices	intended for percutaneous drainage of fluids from body cavities for up to 90 days.
MD 0204, MDS7006	Esophageal Stent Systems	intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulae. Also indicated for stenting refractory benign esophageal strictures for up to 6 months.
MD 0204, MDS7006	Tracheobronchial Stent Systems	indicated for the use in the treatment of tracheobronchial strictures and airway compressions (stenosis) produced by malignant neoplasms
MD 1104, MDS7006	Bipolar Coagulation Probe and related accessories	Probes function as conventional electro-coagulation devices when supplied with current from a standard bipolar electro-surgical generator. The probes are intended to provide hemostasis throughout the gastrointestinal tract.
MD 0204, MDS7006	Peritoneal Dialysis Catheters	intended for implantation for more than 30 days to carry fluid into and out of the abdomen

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Class IIb		
MD1104, MDS7006	Rotating Tip Venous Infusion Catheters	indicated for infusion of physician-specified agents in the peripheral vasculature including for endovascular occlusion of incompetent veins in patients with superficial venous reflux.
MD 0106, MDS7006	Peritoneal Dialysis Catheter Accessories and Kits	indicated for embedding the external portion of most PD catheters subcutaneously in anticipation of future retrieval of the part of the catheter
MD 0202, MDS7006	Bone Cement and Saturate Mixing System	intended for use in treatment of pathological fractures of the vertebrae using vertebroplasty or kyphoplasty procedure
MD 1402, MDS7006	RF Tumor Ablation Systems for orthopedic applications (instruments and kits)	intended for the ablation of tumor within the vertebral body. It heats targeted tissue in contact with the electrode
MD 1402 (non-sterile)	RF Generator	intended to generate and control the delivery of RF energy for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body

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Class IIb		
MD 0204, MDS7006	Embolization Particles	used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs)
MD 0103, MD 0204, MD 1104, MD 0106, MD 0202, MD 1402, MD 0201, MDS 7006	Procedure kits/packs	a collection of medical devices packaged, labeled, and sterilized together for the convenience of the clinician to support various procedures.
MD 0201, MDS7006	Endovascular Stent Graft Systems	indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis outflow circuit of an arteriovenous (AV) fistula or AV graft.
Class IIa		
MD 0102, MDS7006	Infusion Catheters	NA for class IIa devices
MD 0102, MDS7006	Drainage Devices	NA for class IIa devices
MD 0104, MDS7006	Digital Inflation Syringes	NA for class IIa devices
MD 0106, MDS7006	Introducer Devices	NA for class IIa devices
MD 0106, MDS7006	Manifolds, Stopcocks, Rotating Adapters, Flow Switch, TRAM	NA for class IIa devices
MD 0106, MDS7006	Vessel Dilators	NA for class IIa devices
MD 0106, MDS7006	Valve Adapter	NA for class IIa devices
MD 0102, MDS7006	Tubing	NA for class IIa devices
MD 0104, MDS7006	Transducers	NA for class IIa devices

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Class IIa		
MD 0106, MDS7006	Merit Angioplasty Pack	NA for class IIa devices
MD 0106, MDS7006	Hemostasis Devices	NA for class IIa devices
MD 0106, MDS7006	Sheath Introducers, Dilators, and Obturators	NA for class IIa devices
MD 0106, MDS7006	Angiographic Needles	NA for class IIa devices
MD 0106, MDS7006	Scalpels	NA for class IIa devices
MD 0106, MDS7006	Catheter Extractor Devices	NA for class IIa devices
MD 0102, MDS7006	Contrast Management Devices	NA for class IIa devices
MD 0106, MDS7006	Vascular Trocars	NA for class IIa devices
MD 0106, MDS7006	Guide Wires	NA for class IIa devices
MD 0106, MDS7006	Peritoneal Dialysis Accessories and Kits	NA for class IIa devices
MD 0106, MDS7006	Biopsy Instruments and Accessories	NA for class IIa devices
MD 0106, MDS7006	Graft Accessory Component Kits	NA for class IIa devices
MD 1402, MDS7006	Activation Element	NA for class IIa devices

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Class IIa		
MD 1402 (non-sterile)	Multiplex Controllers	NA for class IIa devices
MD 0106, MDS7006	Orthopedic Surgical Instruments	NA for class IIa devices
MD 0106, MDS7006	Percutaneous Transluminal Angioplasty (PTA) Catheters	NA for class IIa devices
MD 0108, MDS7006	Caps for Disinfection of Vascular Access Connectors	NA for class IIa devices
MD 0106, MDS7006	Merit Microcatheters	NA for class IIa devices
MD 0106, MDS7006	Bone Cement Delivery Devices and Accessories	NA for class IIa devices
MD 0102, MDS7006	Angiographic Peripheral Catheters	NA for class IIa devices
MD 0102, MD 0104, MD 0106, MD 0108, MD 1402, MDS7006	Procedure Kits/Packs	NA for class IIa devices
Class Is		
MDS7006	Infusion Systems	NA for class Is devices
MDS7006	Compression Devices	NA for class Is devices
MDS7006	Labeling Sets	NA for class Is devices

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Class Is		
MDS7006	Drainage, Waste, and Sharps Collection Devices	NA for class Is devices
MDS7006	Valves and Check Relief Valves	NA for class Is devices
MDS7006	Catheter Fixation Devices	NA for class Is devices
MDS7006	Contrast Management Devices	NA for class Is devices
MDS7006	Flush Devices	NA for class Is devices
MDS7006	Angioplasty Packs	NA for class Is devices
MDS7006	Procedure Kits/Packs	NA for class Is devices
MDS7006	Connection Tubes	NA for class Is devices
MDS7006	Analog Inflation Syringes	NA for class Is devices
MDS7006	Torque Devices, Suture Retention Devices	NA for class Is devices
MDS7006	Surgical/general purpose organizers and accessories	NA for class Is devices
MDS7006	Balloon Inflation Systems	NA for class Is devices
MDS7006	Peritoneal Dialysis Accessories and Kits	NA for class Is devices
MDS7006	Nasopharyngeal Swabs	NA for class Is devices
MDS7006	Non-Vascular Balloon Catheter Systems	NA for class Is devices

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Class Im		
MD 0104 (non-sterile)	Syringes	NA for class Im devices
MD 1301 (non-sterile)	Balloon Inflation Systems and Related Accessories	NA for class Im devices
MD 0104 (non-sterile)	Tracheal Measuring Devices	NA for class Im devices
Class Is,m		
MD 0104, MDS7006	Syringes	NA for class Im devices

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