



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):

Albert Roossien, Regulatory Lead

First Issued: **2008-10-03**

Date: **2019-02-08**

Expiry Date: **2023-10-02**

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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, biliary 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.

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 and all related accessories.

Those aspects of Annex II related to metrology in the manufacture of syringes, pressure monitors, 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	Merit Microcatheters	See CE 553250
MD 0106, MDS7006	EN Snare Endovascular 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	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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Class IIb		
MD 0200, MDS7006	Biliary Catheter (RBC), Biliary Drainage Cath. (RBDC), CirQ Nephrostomy Catheter	intended for drainage of bile within the biliary system
MD 0200, MDS7006	ReSolve Locking Catheter (RLC)	intended for percutaneous drainage of fluids from body cavities for up to 90 days.
MD 0106, MDS7006	ALIMAXX-ES, EndoMAXX, EndoMAXX EVT	used in the treatment of malignant neoplasms for the purpose of palliating the airway.
MD 0106, MDS7006	AERO Tracheobronchial Stent, AeroMINI, AERO Delivery System	indicated for the use in the treatment of tracheobronchial strictures and airway compressions (stenosis) produced by malignant neoplasms
MD 0106, MDS7006	Biliary Stents & Delivery System: ALIMAXX-B	indicated for the palliation of malignant strictures in the biliary tree
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 0102, MDS7006	Flex-Neck® Classic, Infant, ARC, ExxTend Catheters	intended for implantation for more than 30 days to carry fluid into and out of the abdomen

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Class IIb		
MD 0106, MDS7006	Peritoneal Dialysis Catheter Embedding Tool	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	StabilIT ER2 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	SpineSTAR Tumor Ablation Systems (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)	MetaSTAR 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
MD 0200, MDS7006	BioSphere Bearing nsPVA	used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs)
MD 0202, MDS7006	StabilIT Vertebral Augmentation & Vertebroplasty Kits (Class IIb kits under article 12)	for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure

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Class IIb		
MD 0202, MDS7006	StabiliT Vertebral Augmentation & Vertebroplasty Kits (Class IIb kits under article 11)	for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure
Class IIa		
MD 0102, MDS7006	Fountain & Mistique Infusion Catheters	NA for class IIa devices
MD 0102, MDS7006	One Step Centesis Drainage Catheter	NA for class IIa devices
MD 0102, MDS7006	ReSolve Non-Locking Catheter (RNL), Resolve Dilator	NA for class IIa devices
MD 0104, MDS7006	Intelliflator & Merit Monitor (IntelliSystem), DiamondTOUCH, Monarch, Blue Diamond, Endotek Digital Inflation Syringes	NA for class IIa devices
MD 0106, MDS7006	Introducer, Mini Access, Radial, Plastic Jacket Guide Wires	NA for class IIa devices
MD 0106, MDS7006	MAXXWIRE & ENDOWIRE (Aero) Guide Wires	NA for class IIa devices
MD 0106, MDS7006	Manifolds, Stopcocks, Rotating Adapters, Flow Switch, TRAM	NA for class IIa devices
MD 0106, MDS7006	MAK/SMAC, MAK-NV, Vessel Dilator	NA for class IIa devices
MD 0106, MDS7006	Valve Adapter	NA for class IIa devices
MD 0102, MDS7006	High Pressure Contract Injection and Pressure Monitoring Tubing	NA for class IIa devices
MD 0104, MDS7006	MeriTrans™ and Argotrans Disposable Transducers	NA for class IIa devices

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IIa

NBOG code(s)	Device description	Intended purpose
Class IIa		
MD 0106, MDS7006	Merit Angioplasty Pack (MAP Kits)	NA for class IIa devices
MD 0106, MDS7006	FLO50, PhD, Passage, Access-9, AccessPLUS, DoublePlay, MBA, MBA Plus, Honor, FLO30, FLO40, FLO40XR Hemostasis Valves	NA for class IIa devices
MD 0106, MDS7006	Prelude (PSI & PRO), HVA, PreludeEASE, Prelude short Sheath, Dilator & Obturator	NA for class IIa devices
MD 0106, MDS7006	Advance™ Merit Angiographic Needles	NA for class IIa devices
MD 0106, MDS7006	Futura™ Safety Scalpel	NA for class IIa devices
MD 0106, MDS7006	OuTake Catheter Extractor Device	NA for class IIa devices
MD 0102, MDS7006	Contrast Management Systems (high pressure use)	NA for class IIa devices
MD 0102, MDS7006	CT Transfer Set - FAS	NA for class IIa devices
MD 0106, MDS7006	Flow Guard™ Valved Peelable Introducer	NA for class IIa devices
MD 0106, MDS7006	Hart Chiba & Trocar Style Needles	NA for class IIa devices
MD 0106, MDS7006	Merit Advance Angiographic Safety Needles	NA for class IIa devices
MD 0106, MDS7006	Laureate Guide Wire (peripheral and urological)	NA for class IIa devices
MD 0106, MDS7006	Peritoneal Dialysis Implantation Kits	NA for class IIa devices
MD 0106, MDS7006	Corvocet Coaxial Introducer and Biopsy System	NA for class IIa devices
MD 0106, MDS7006	HeRO Accessory Kit	NA for class IIa devices
MD 0106, MDS7006	Hydraulic Assembly and Hydraulic Master Syringe Assembly	NA for class IIa devices
MD 1402, MDS7006	Activation Element	NA for class IIa devices

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IIa

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Class IIa		
MD 1402 (non-sterile)	Multiplex Controllers	NA for class IIa devices
MD 0103, MDS7006	StabiliT and STAR Instruments	NA for class IIa devices
MD 0106, MDS7006	Advocate PTA Balloon Catheter	NA for class IIa devices
MD 0108, MDS7006	DualCap System	NA for class IIa devices
MD 0106, MDS7006	Osseoflex Access Cannulas and Stylets	NA for class IIa devices
MD 0106, MDS7006	Osseoflex Steerable Needles	NA for class IIa devices
MD 0106, MDS7006	Bone Filler Devices	NA for class IIa devices
MD 0106, MDS7006	Bone Drills	NA for class IIa devices
MD 0106, MDS7006	Pursue (Hi-Lex) Microcatheter	NA for class IIa devices
MD 0106, MDS7006	Osseoflex Cement Delivery System	NA for class IIa devices
MD 0106, MDS7006	Bone Marrow Aspiration Needle	NA for class IIa devices
Class Is		
MDS7006	Squirt Fluid Dispensing System	NA for class Is devices
MDS7006	External Vascular Compressors / RadStat Radial Artery Compression System; Compression Discs	NA for class Is devices
MDS7006	Tags / PAL Pen and Labels; Custom PAL Labels; PAL Pen	NA for class Is devices

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MDS7006	Basins / Backstop® Disposal Basin; Ministop Disposal Basins; BackStopPlus Disposal Basis; MiniStopPlus Disposal Basin; Triple Play™ Disposal Basin; Dugout® DisposalBasin; RingMaster Guide Wire Basin	NA for class Is devices
MDS7006	Valves / Check Relief Valve; In - Line Check Relief Valve [CRV] Caotiva® Blood Containment Device	NA for class Is devices
MDS7006	Catheter Tubeholders / Revolution Catheter Securement Device	NA for class Is devices
MDS7006	Fluid Administration Set; Fluid Administration Spike; Fluid Management Tube	NA for class Is devices
MDS7006	Merit Miser Contrast Management System	NA for class Is devices
MDS7006	Continuous Flush Devices	NA for class Is devices
MDS7006	Merit Angioplasty Packs	NA for class Is devices
MDS7006	Waste Disposal System	NA for class Is devices
MDS7006	Merit Disposal Depot	NA for class Is devices
MDS7006	Shortstop and Shortstop Advantage Temporary Sharps Holders	NA for class Is devices
MDS7006	Procedure Packs (Custom Kits); Rapid Response Kits	NA for class Is devices
MDS7006	Connection Tubes	NA for class Is devices
MDS7006	Syringes	NA for class Is devices

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Class Is		
MDS7006	Syringes	NA for class Is devices
MDS7006	Merit Drainage Depot	NA for class Is devices
MDS7006	Basix™ Inflation Syringe; BasixCOMPAK Inflation Syringe; BasixTOUCH Inflation Syringe	NA for class Is devices
MDS7006	Angiography and Angioplasty Procedures Accessories of Class I Sterile / RXP® Rapid Exchange Prep Syringe; Guide Wire Insertion Tool; Pin Vice Torque Device; H2O TORQ Device; SeaDragon Torque Device	NA for class Is devices
Class Im		
MD 1301 (non-sterile)	Monitors / IntelliSystem® II Color Monitor	NA for class Im devices
MD 0104 (non-sterile)	AeroSIZER Stent Measuring System	NA for class Im devices

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