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: **2021-02-17** Expiry Date: **2023-10-02**

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By Royal Charter

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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Supplementary Information to CE 541900

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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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NBOG code(s)	Device description	Intended purpose
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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NBOG code(s)	Device description	Intended purpose
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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NBOG code(s)	Device description	Intended purpose
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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Date	Reference Number	Action
03 October 2008	7277386	First issue – Transfer from another Notified Body
17 April 2009	7357779	Addition of Caridian BCT Inc as an ETO Sterilization subcontractor and addition of EU Representative to the services supplied by Merit Medical Ireland Ltd, Galway.
14 September 2009	7432256	Addition of significant subcontractor Martech Medical's facility in Mexico for the manufacture of all ProGuide™ Dialysis Catheters.
14 September 2009	7440799	Addition of significant subcontractor GMACO Ltd's facility in Shizuoka for the supply of all Maestro™ Microcatheters.
17 December 2009	7461861	Extension to Scope to include Endovascular Snare Systems. Addition of Pelham Plastics Inc as a manufacturing subcontractor.
19 January 2010	7466646	The addition of Merit Medical Systems Inc. Chester as a Manufacturing and Control of Sterilization subcontractor.
07 July 2010	7536831	Addition of Contract Medical International, GmbH for the fabrication of Embolectomy Catheters
30 March 2012	7762609	Transfer of all products from Merit Medical and Merit Endotek's Annex V and Annex II.3 certificates CE 542368, CE 551111 and CE 558041. Updates to the significant subcontractor list.

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03 August 2012	7816473	Extension to scope to add "stent positioning system intended for coronary and renal interventional procedures" and addition of significant subcontractor Nitinol Devices and Components, Inc. in Fremont, USA, for the manufacture of the Ostial Pro device. Addition of Lemco Enterprises Inc. as a significant subcontractor for sterilization of the Ostial Pro device.
25 September 2012	7900690	Addition of "Design" to the activities performed by Merit Medical Ireland Ltd.
03 October 2012	7858357	Addition of 'Coated and Uncoated' to guide wires in the scope and removal of 'vascular'. Update to the name and address for Terumo BCT Sterilization Services. Addition of significant subcontractors Admedes, Inc. and STERIS Isomedix Service in Temecula, CA. Update to the Integra Biotechnical address.
16 January 2013	7931475	Addition of Peritoneal Dialysis Catheters to the scope and addition of significant subcontractor Parker Medical Systems.
19 April 2013	7943363	Addition of Embolic Microspheres to the certificate scope. Addition of Biosphere Medical SA and Ionisos as significant subcontractors.

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27 September 2013	8012823	Certificate renewal. Addition of significant subcontractors Perouse Medical in Irigny, France. for the manufacture of H2O Torque device, ConvaTec Limited in Flintshire, UK, for the manufacture of StayFIX securement device, Merit Medical Systems, Inc. in Malvern, USA, for manufacture (numerous devices), QXMeidcal, LLC in St Paul, USA, for the manufacture of SureCross Catheters, and Steris Isomedix Services in Minneapolis, USA for sterilization. Change Embolic Microshperes to Embolization Particles in the certificate scope to clarify terminology. Correct subcontractor names / addresses for Integra Biotechnical, Ionisos, Merit Medical UT USA, Nitinol Devices CA USA. Change name of subcontractor GMACO Ltd. To Asahi-Intecc GMA Co., LTD. Remove subcontractors Lemco Enterprises Inc. and Merit Medical Murray, Utah from significant subcontractors list. Relocate "compression devices" from paragraph 1 to paragraph 2 in the scope.
17 April 2014	8149114	Update to add Merit Medical Systems in Houston, TX and Steris Isomedix Services in Whippany, NJ to the list of significant subcontractors.

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Date	Reference Number	Action
15 April 2015	8313610	Removal of subcontractors Contract Medical (Dresden, Germany), ConvaTech (Flintshire, UK), Merit (Netherlands), Merit (Chester VA), Merit (Angleton TX), Merit (Malvern PA), Nitinol Devices (Fremont CA), Parker Medical (Merrillville IN), Perouse Medical (Irigny France) and Sterigenics (Santa Teresa NM). Addition of Lake Region Medical (New Ross, Ireland) to critical subcontractors list. Address correction of subcontractor Ashai-Intecc.
10 August 2015	8348914	Addition of Merit (Maquiladora Mexico) as significant subcontractor and removal of Integra Biotechnical as a subcontractor.
13 November 2015	8427572	Removal of subcontractors Interplex Medical (Milford, Ohio), QX Medical (St Paul, Minnesota) and Steris Isomedix (Minneapolis, Minnesota).
27 April 2016	8453449	Addition of "Biopsy Instruments and Accessories" to scope. Addition of Merit (Chester, VA) to critical subcontractor list.
31 May 2016	8533934	Addition of 'sterile' and 'vascular grafts and graft accessory component kits' to the certificate scope. Added Bard Peripheral Vascular (Tempe AZ) as crucial supplier.

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12 December 2016	8645172	Addition of "orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments and RF tumor ablation systems for orthopedic applications" to scope. Removal of subcontractor Martech Medical Products (Harleysville, PA), Sterigenics (Willowbrook, IL) and Steris Isomedix (Whippany, NJ). Addition of subcontractor Medron, Inc. (Salt Lake City, UT) for the activity of "Manufacture", Apical Instruments (Mountain View, CA) for the activity of "Manufacture", LZ-Form KFT (Ajka, Hungary) for the activity of "Manufacture", Minnetronix (St. Paul, MN) for the activity of "Manufacture", Tecres S.P.A. (Verona, Italy) for the activity of "Manufacture", Vention Medical (Costa Rica) for the activity of "Manufacture" Synergy Health (County Mayo, Ireland) for the activity of "Gamma Sterilization", and Piolax Medical (Yokohama, Japan) for the activity of "Manufacture".
27 April 2017	8636817	Addition of "percutaneous transluminal angioplasty (PTA) catheters" to scope. Addition of Arravasc Limited (Galway, Ireland) for the activity of "Finished Device Supplier". Addition of activity "Control of Sterilization" to Merit Medical Ireland Ltd. (Galway, Ireland).
16 August 2017	8732858	Update scope to include disinfectant caps. Add Health Line International Corporation for the service of Manufacture. Add introducer needle and angiographic needle to the scope for clarification.

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03 October 2017	8675156	Addition of Akita Sumitomo Bakelite Co., Ltd. for the activity of "Finished Device Supplier".
26 October 2017	8814857	Addition of subcontractor, Sterigenics Belgium (Petit-Rechain) for the activity of "ETO Sterilization". Change of subcontractor 'name, address' from Vention Medical (Costa Rica) to MedPlast Medical Inc. (Costa Rica).
08 December 2017	8867282	Changed activity for subcontractor Asahi-Intecc from "Supply" to "Manufacture" to align with new healthcare subcontractor activities.
18 May 2018	8887508	Removal of subcontractors Apical Instruments, MedPlast Medical and Pelham Plastics. Addition of subcontractors Centurion Medical Products Corporation for the activity of "ETO Sterilization", Structure Medical LLC for the activity of "Manufacture", HI-LEX Corporation (Hyogo, Japan) for the activity of " Manufacture", and Synergy Health AST, LLC for the activity of "E-Beam Sterilization", DM Pack for the activity of "Packaging", ECP Entegris Cleaning Process SAS for the activity of "Packaging", P2A Medical for the activity of "Packaging", and Sterilab for the activity of "ETO Sterilization". Correct subcontractor address of Akita Sumitomo Bakelite. Change of subcontractor name from Steris Corp Isomedix Services to Isomedix Operations, Inc. Change of subcontractor name from Steris Isomedix Services to Isomedix Operations, Inc.

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Date	Reference Number	Action
01 October 2018	9625216	Certificate Renewal. Reduction of scope to remove bipolar coagulation probes and accessories. Change activity "Finished Device Supplier" to "Manufacture" for Akita Sumitomo Bakelite Co. and Arravasc Limited. Addition of subcontractors Mannan Medical Products, Inc. (Wheeling, IL) and Merit Medical Systems, Inc. (Malvern, PA) for the activity of "Manufacture". Correct spelling error Martech Medical "Prodcuts" to Martech Medical "Products".
21 November 2018	9676318	Extension of scope to include 'bipolar coagulation probes and all related accessories.' Addition of product table. Removal of subcontractor Mannan Medical Products. Correct subcontractor address of Piolax Medical Devices.
16 January 2019	9647078	Addition of critical subcontractor Sterilization Services of Virginia.
08 February 2019	7780616	Traceable to NB 0086.

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Date	Reference Number	Action
09 May 2019	9749221	Extension to scope to add "rotating tip venous infusion catheters". Add significant subcontractors: Bridgemedica, Professional Contract Sterilization Inc. and IONISOS Dagneux. Add E Beam sterilization as a service supplied for Synergy Tullamore. Update product table to use "Guide Wires" and "Merit Microcatheters" subcategory names. Add "Angiographic Peripheral Catheters" to device table. Correct certificate errors: correct "Class IIa" headings in device table, correct spelling error Martech Medical "Prodcuts" to "Products" and correct address for Piolax Medical Devices Inc. "Yokahama" to "Yokohama" and remove "-ken" after "Kanagawa".
14 October 2019	9716685	Extension to scope to add non-sterile syringes, stopcocks, manifolds, and hemostasis devices. Device table revisions for Class IIb, IIa, Is, Im, and Is,m to list device categories / groups consistent with scope statement instead of specific brand names. Corrections to Intended Purpose for Esophageal and Tracheobronchial Stent Systems. List product subcategories / groups on supplementary information tables IIb, IIa and Is that are in scope but have been inadvertently omitted from the tables - Procedure kits/packs (IIb and IIa), Surgical/general purpose organizers and accessories (Is). Removed ArraVasc Limited as a significant subcontractor.
08 December 2019	3108477	Update description of CE 555846 and CE 590890 to include EMPOWER snare systems. Addition of Synergy Health Ede BV, Etten-Leur, The Netherlands for service of gamma sterilization.
01 April 2020	3157332	Correct scope and device table to include class Is peritoneal dialysis accessories and kits.

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Date	Reference Number	Action
21 May 2020	3221049	Extension to scope for "endovascular stent graft systems" and addition to device table.
11 June 2020	3207131	Extension to scope for "nasopharyngeal swabs" and addition to device table. Addition of subcontractor Isomedix Operations, Inc. 1435 Isomedix Place, El Paso, Texas. Correction of device table to include "non-vascular balloon catheter systems" already present in scope.
09 September 2020	3284131	Removal of CE 553250 Merit Microcatheters from device table.
17 November 2020	3310398	Removal of biliary stent systems from scope and device table. Addition of subcontractor Synergy Health Ede BV, Morsestraat 3, The Netherlands. Code correction for embolization particles to MD 0204.
17 February 2021	3366774	Removal of Merit Medical Systems, Inc. West Jordan and Malvern subcontractors.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
01 March 2022	3633732	Scope reduced to remove "percutaneous transluminal angioplasty (PTA) catheters". The class IIa Percutaneous Transluminal Angioplasty (PTA) Catheters are removed from the device table.

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Date	Reference Number	Action
07 February 2023	3850930	Scope reduced to remove "peritoneal dialysis catheters, accessories and kits". The Class Is/IIa/IIb Peritoneal Dialysis Catheters, Accessories and Kits are removed from the device table. Removal of subcontractors for manufacture and sterilization of Bone Marrow Aspiration Needle, Bone Biopsy, Osseoflex, ClariVein, and Endotek Biliary Stent devices.
07 April 2023	3895671	The Class IIb RF Generator and Class IIa Multiplex Controllers are removed from the device table. Removal of subcontractor for manufacture of MetaSTAR RF Generator and Multiplex Controllers.

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07 April 2023

Merit Medical Systems, Inc.
1600 West Merit Parkway
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 541900	93/42/EEC Annex II excluding Section 4	3895671	The Class IIb RF Generator and Class IIa Multiplex Controllers are removed from the device table. Removal of subcontractor Minnetronix for manufacture of MetaSTAR RF Generator and Multiplex Controllers.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices