EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 716389 R001

Manufacturer: Merit Medical Systems, Inc.

Address:
1600 West Merit Parkway
South Jordan
Utah
84095
USA

Single Registration Number: US-MF-000001366

EU Authorised Representative: Merit Medical Ireland Ltd.

Address:
Parkmore Business Park West
Galway
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-05-27**

Current Issue Date: **2026-05-05**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	**Intended purpose**
HeRO Graft	See MDR 757768
WRAPSODY Cell-Impermeable Endoprosthesis	See MDR 757905
BioFlo DuraMax with Endexo Technology Chronic Hemodialysis Catheter	See MDR 810831

Class III	**Intended purpose**
Maestro Microcatheters	See MDR 724785
Pursue Microcatheters	See MDR 750456
Prelude Roadster Sheath Introducer	See MDR 778246
Impress and Impress Legato Angiography Catheters	See MDR 757157
HeartSpan and CARDIAGUIDE Transseptal Sheath and Needle	See MDR 785843
Coronary Sinus Guides and Lateral Vein Introducers	See MDR 785161
Prelude Prestige Splittable Sheath Introducer	See MDR 785166
HeartSpan Steerable Sheath Introducer	See MDR 785168
Pericardiocentesis Kit	See MDR 757893
Performa Angiography Catheters	See MDR 756376
Class IIb, Implantable	**Intended purpose**
Resolve Drainage Catheters	See MDR 778416
Aspira Drainage Catheter	See MDR 792293
Tracheobronchial Stent Systems	See MDR 785845
Gastro-intestinal suture devices and systems	See MDR 826063

Class IIb under Rule 12 – Administer and/or remove a medicinal substance	**Intended purpose**
Peripheral Angiographic Devices	Intended for infusion of physician-specified agents into the peripheral vasculature.

Class IIb	**Intended purpose**
Vital Signs Monitoring Instruments	Intended for monitoring of vital physiological parameters.
Peripheral I.V. Catheter Systems	Intended for administering infusions of various therapeutic solutions.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Biopsy Systems and Accessories	Class IIa
Cutting Devices	Class IIa
Devices for Administration, Withdrawal/Drainage and Collection	Class IIa
Vascular Access Devices and Accessories	Class IIa
Non-Vascular Access Devices	Class IIa
Haemodialysis Vascular Access Devices	Class IIa
Caps for Disinfection of Vascular Access Connectors	Class IIa
Digital Inflation Syringes	Class IIa
Instruments for gastro-intestinal endoscopy	Class IIa
Analog Inflation Devices	Class Is, Class Im
Syringes	Class Is, Class Im
Syringes	Class Im
Administration Kits	Class Is
Fluid Collection Devices	Class Is
Torque devices	Class Is
Luer Caps and Covers	Class Is
Catheter Fixation Devices	Class Is
Non-active non-implantable instruments	Class Is
Non-Vascular Balloon Catheter Systems	Class Is
Suture retention devices	Class Is
Drainage, Waste, and Sharps Collection Devices	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-05-27	3061162	Issued.
2022-06-10	3681095	Amended – Correction of address to subcontractor for sterilization. Supplemented – Addition of HeRO Graft.
2022-08-24	3720184	Amended – addition of subcontractors for manufacture and sterilization of ConcierGE devices. Supplemented – Addition of ConcierGE Guiding Catheters.
2023-05-22	3871475	Amended – Removal of list of critical subcontractors and crucial suppliers. An administrative update to the history has been made. Supplemented – Addition of Maestro and Pursue Microcatheters. Addition of device category 'Vascular and Non-Vascular Access Devices and Accessories'.
2024-04-16	30001152	Supplemented – Addition of WRAPSODY Cell-Impermeable Endoprosthesis. Addition of device categories 'Biopsy Systems and Accessories', 'Devices for Administration, Withdrawal, and Collection' and 'Analog Inflation Devices'.
2024-05-03	30158935	Supplemented – Addition of Prelude® Roadster Sheath Introducer. Addition of device groups 'Vital Signs Monitoring Instruments' and 'Peripheral I.V. Catheter Systems'.
2024-12-06	30191939	Supplemented – Addition of generic device group 'Peripheral Angiographic Devices'. Amended – Change of device category name from 'Biopsy Systems and Accessories' to 'Biopsy Systems and Accessories, and Cutting Devices'. Addition of a subcontractor for the manufacturing and a subcontractor for the sterilization for 'Biopsy Systems and Accessories, and Cutting Devices'.

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Date	Reference number	Action
2025-01-28	30292215	Supplemented – Addition of 'Administration Kits' and 'Fluid Collection Devices'. Amended – change of device category name from 'Devices for Administration, Withdrawal, and Collection' to 'Devices for Administration, Withdrawal/Drainage and Collection'.
2025-06-04	30382978	Supplemented – Addition of 'Impress Angiography Catheters' and 'Impress Legato Angiography Catheters'.
2025-06-17	30338871	Supplemented – Addition of 'BioFlo DuraMax with Endexo Technology Chronic Hemodialysis Catheter' and 'Torque devices'.
2025-11-10	30339265	Supplemented – Addition of 'HeartSpan® Fixed Curve Braided Transseptal Sheath', 'CARDIAGUIDE™ Fixed Curve Sheath', 'Primovo Fixed Curve Transseptal Sheath', 'HeartSpan® Transseptal Needle', 'CARDIAGUIDE™ Transseptal Needle', 'Primovo Transseptal Needle', 'SafeSheath CSG', 'Worley Advanced CSG', 'SafeSheath Worley LVI', 'Worley Advanced LVI', 'Situs Target', 'Situs LDS 2', 'Prelude Prestige™ Splittable Sheath Introducer', 'HeartSpan® Steerable Sheath Introducer', 'Pericardiocentesis Kit', 'ReSolve Biliary Locking Drainage Catheter', 'ReSolve Locking Drainage Catheter', 'ReSolve Mini Locking Drainage Catheter', 'Aspira Drainage Catheter', 'Luer Caps and Covers', 'Catheter Fixation Devices', 'Non-active non-implantable instruments', 'Non-Vascular Balloon Catheter Systems'.
2026-02-10	30338867	Supplemented – Addition of 'Performa Angiography Catheters', 'MERIT AERO/ MERIT AERO DV/ MERIT AEROmini Tracheobronchial Stent System', 'Suture retention devices' and of the device categories 'Caps for Disinfection of Vascular Access Connectors', 'Digital Inflation Syringes'.

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Date	Reference number	Action
2026-03-02	30634959	Supplement – Addition of 'EsophyX Z+ Fastener Delivery Device with SerosaFuse Implantable Fasteners/ EsophyX Z+ Fastener Delivery Device with SerosaFuse Fastener/ EsophyX Z+ with SerosaFuse Implantable Fasteners/ SerosaFuse Fasteners with EsophyX Z+ Fastener Delivery Device/ EsophyX Z+ System', 'SerosaFuse Implantable Fasteners/ SerosaFuse Fasteners', 'Drainage, Waste, and Sharps Collection Devices' and of device category 'Instruments for gastro-intestinal endoscopy'.
Current	30538996	Restricted – Removal of ConcierGE Guiding Catheters, Primovo Fixed Curve Transseptal Sheath and Needle. Amended – Division of the device category 'Vascular and Non-Vascular Access Devices and Accessories' into 'Haemodialysis Vascular Access Devices', 'Non-Vascular Access Devices', and 'Vascular Access Devices and Accessories'. Division of the device category 'Biopsy Systems and Accessories, and Cutting Devices' into 'Biopsy Systems and Accessories' and 'Cutting Devices'. Administrative Device Table updates. Re-Issued – Certificate Renewal.

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