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

08 FEB 2024

Notified Body Confirmation Letter

Reference: EU2023-607/ID 704322

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number (if available): US-MF-000001366; US-PR-000008345

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written

agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HeRO Graft	Class III	N/A	CE 541900; NB 2797; CE 650631, NB 2797
HeRO Accessory Kit (ACK)	Class IIa	N/A	CE 541900; NB 2797
EN Snare Endovascular Snare System **EMPOWER Tri-Loop Snare System**	Class III	N/A	CE 541900; NB 2797; CE 555846, NB 2797
InQwire Diagnostic Guide Wires	Class III	N/A	CE 541900; NB 2797; CE560101, NB 2797
Concierge Guiding Catheter	Class III	N/A	CE 541900; NB 2797; CE 538238, NB 2797
Aspira Peritoneal Drainage Catheter	Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Aspira Pleural Drainage Catheter	Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Aspira Drainage Bag	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Aspira Drainage Bottle	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Aspira Valve Assembly	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Aspira Luer Adaptor	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Aspira Universal Tubing Adaptor	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Aspira Drainage Catheter Accessory Devices: Suture Wing	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Aspira Drainage Catheter Accessory	Class IIa	N/A	CE 541900; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Devices: Non-vascular Dilators			
Aspira Drainage Catheter Accessory Devices: Prelude SNAP 16.5 Fr Splitable Introducer	Class IIa	N/A	CE 541900; NB 2797
Aspira Drainage Catheter Accessory Devices: Tunneler	Class IIa	N/A	CE 541900; NB 2797
Splash Hydrophilic Guide Wires	Class III	N/A	CE 541900; NB 2797
Impress and Impress Legato Angiographic Catheters	Class III	N/A	CE 541900; NB 2797; CE538238, NB 2797
Blue Diamond Inflation Syringe	Class IIa	N/A	CE 541900; NB 2797
Performa, Performa Vessel Sizing	Class III	N/A	CE 541900; NB 2797; CE 538238, NB 2797
ReSolve Biliary Locking Drainage Catheter (RBC & RBDC) **ReSolve Locking Catheter (RLC)** **ReSolve Mini Locking Drainage Catheter (RML)**	Class IIb implantable non-WET	N/A	CE 541900; NB 2797
InQwire Amplatz Super Stiff Guidewire	Class III	N/A	CE 541900; NB 2797
AERO Tracheobronchial Stent **AEROmini**	Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Pursue Microcatheter	Class III	N/A	CE 541900; NB 2797
Wrapsody CVO Stent Graft System	Class III	N/A	CE 541900; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Pericardia Centesis Catheter (PCC)	Class III	N/A	CE 541900; NB 2797, CE 541480, NB 2797
Analog Inflation Syringes: **- basixCompak** **- basixTouch** **- basixTouch40** **- BIG60** **- BIG60 Alpha**	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
ReSolve Non-Locking Catheter (RLC)	Class IIa	N/A	CE 541900; NB 2797
ReSolve Dilator (RLC accessory)	Class IIa	N/A	CE 541900; NB 2797
Piston Syringes (Medallion, VacLok, VacLok AT, Zeonex, CCS, Triboglide)	Class I device with a measuring function	N/A	CE 541900; NB 2797
Piston Syringes non-sterile (Medallion, VacLok, VacLok AT, Zeonex, CCS, Triboglide)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
MeriTrans Pressure Monitoring Transducer	Class IIb excluding Class IIb implantable non-WET	N/A	CE 541900; NB 2797
TRAM/TRAM-P (Manifold w/integrated pressure transducer)	Class IIb excluding Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Biopsy CorVocet Biopsy System	Class IIa	N/A	CE 541900; NB 2797
Biopsy – Achieve & Pink Achieve Automatic Biopsy System	Class IIa	N/A	CE 541900; NB 2797
Biopsy – CorVocet Coaxial Introducer	Class IIa	N/A	CE 541900; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ClariVein OC Infusion Catheter	Class IIb excluding Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Flow Switch (sterile & non-sterile)	Class IIa	N/A	CE 541900; NB 2797
Manifold (sterile & non-sterile)	Class IIa	N/A	CE 541900; NB 2797
Stopcock (sterile & non-sterile)	Class IIa	N/A	CE 541900; NB 2797
Rotating Adaptor (sterile & non-sterile)	Class IIa	N/A	CE 541900; NB 2797
Go2Wire	Class III	N/A	CE 541900; NB 2797
Fountain ValveTip Infusion Catheter	Class IIb excluding Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Drainage Catheters: - **One Step Centesis** - **Cen Step**	Class IIa	N/A	CE 541900; NB 2797
Prelude Large OD Introducer Guide Wires	Class IIa	Lake Region Supplied Peripheral Guide Wires	CE 541900; NB 2797
Prelude Plastic Jacket Guide Wire	Class IIa	N/A	CE 541900; NB 2797
Introducers (MAK, SMAK)	Class IIa	N/A	CE 541900; NB 2797
Introducers (MAK NV)	Class IIa	N/A	CE 541900; NB 2797
Valve Adapter (VA-40)	Class IIa	N/A	CE 541900; NB 2797
Tubing (HP, PM)	Class IIa	N/A	CE 541900; NB 2797
MAP™ Hemostasis Valves	Class IIa	N/A	CE 541900; NB 2797
AccessPLUS / DoublePlay Hemostasis Valves (sterile & non-sterile)	Class IIa	N/A	CE 541900; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
MBA Hemostasis Vlave (Sterile & non-sterile)	Class IIa	N/A	CE 541900; NB 2797
Honor Hemostasis Valve (sterile & non-sterile)	Class IIa	N/A	CE 541900; NB 2797
PhD Hemostasis Valve & PhD with side arm tubing **Hemostasis Valve (sterile & non-sterile)**	Class IIa	N/A	CE 541900; NB 2797
FLO30 Hemostasis Valve	Class IIa	N/A	CE 541900; NB 2797
FLO40XR Hemostasis Valve	Class IIa	N/A	CE 541900; NB 2797
FLO50 Hemostasis Valve	Class IIa	N/A	CE 541900; NB 2797
Prelude Sheath Introducer (PSI/PRO)	Class IIa	N/A	CE 541900; NB 2797
Prelude Two-Part Needle	Class IIa	Nipro Safelet Cath (2-part access needle)	CE 541900; NB 2797
Prelude Sheath Introducer (EASE, IDEAL, Choice HVA)	Class IIa	N/A	CE 541900; NB 2797
Prelude Sheath Introducer Dilator/Obturator	Class IIa	N/A	CE 541900; NB 2797
Prelude Sheath Introducer Hemostasis Valve Adaptor (HVA)	Class IIa	N/A	CE 541900; NB 2797
Advance Needles	Class IIa	N/A	CE 541900; NB 2797
Futura Safety Scalpel	Class IIa	N/A	CE 541900; NB 2797
CT Transfer Set	Class IIa	N/A	CE 541900; NB 2797
Dual Cap System	Class IIa	N/A	CE 541900; NB 2797
Temno Biopsy Device & Adjustable Coaxial Temno (ACT)	Class IIa	N/A	CE 541900; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Temno Biopsy Evolution	Class IIa	N/A	CE 541900; NB 2797
Temno Biopsy – Universal Coaxial Introducer Needle	Class IIa	N/A	CE 541900; NB 2797
Temno Elite Biopsy System	Class IIa	N/A	CE 541900; NB 2797
Fastbreak Connector	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Contrast Management System (CMS)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Fluid Administration Sets (FAS) (not hight pressure injected)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
BackStop ® Closed Waste Basin, BackStop® Plus Closed Waste Basin, MiniStop (sterile & non-sterile)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Check Relief Valves (CRV)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Merit Disposal Depot™ (MDD)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
ShortStop Temporary Sharps Holder®, ShortStop Advantage® (sterile & non-sterile)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Pin Vise	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Sea Dragon / Sea Dragon II	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
StayFIX® Fixation Device	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Merit Drainage Depot / Bags (MDD) (sterile & non-sterile)	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Esophageal Balloon Dilation Catheters: Fixed Wire, Wire Guided	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Pulmony Balloon Dilation Catheter	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
PreludeSYNC DISTAL and PreludeSYNC Radial Compression Devices	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Safeguard® Pressure Assisted Device 12 cm; Safeguard® Pressure Assisted Device 24 cm; Safeguard® CRM **Safeguard® Focus**	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Molded Caps and Covers	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Molded Luer Connectors	Class IIa	N/A	CE 541900; NB 2797
Bearing nsPVA Embolization Particles	Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Slip-Not Suture Retention Device	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
MAK Guidewire (vascular and non-vascular)	Class IIa	Lake Region Peripheral Guide Wires	CE 541900; NB 2797
Prelude Small OD Introducer Guidewire	Class IIa	Lake Region Peripheral Guide Wires	CE 541900; NB 2797
Wire Insertion Tool – Metal and Plastic	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Surgical Procedure Kits	Class I device placed on the market in sterile condition	N/A	CE 541900; NB 2797
Surgical Procedure Kits	Class I device with a measuring function	N/A	CE 541900; NB 2797
Surgical Procedure Kits	Class IIa	N/A	CE 541900; NB 2797
Surgical Procedure Kits	Class IIb excluding Class IIb implantable non-WET	N/A	CE 541900; NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Surgical Procedure Kits	Class IIb implantable non-WET	N/A	CE 541900; NB 2797
Surgical Procedure Kits	Class III	N/A	CE 541900; NB 2797
Maestro Microcatheter	Class III	N/A	CE 541900; NB 2797
ONE Snare™ Endovascular Snare System **ONE Snare™ Endovascular Microsnare System** **EMPOWER Single Loop Snare System**	Class III	N/A	CE 541900; NB 2797; CE 590890, NB 2797
True Form Reshapable Guidewire	Class III	N/A	CE 541900; NB 2797; CE 669204, NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HeartSpan Transseptal Needle & Stylet Set	Class III	N/A	3809162CE01; NB# 0344 3809162DE02; NB# 0344
HeartSpan Fixed Curve Braided Transseptal Sheath	Class III	N/A	3809162CE01; NB# 0344 3809162DE02; NB# 0344
HeartSpan Steerable Sheath Introducer	Class III	N/A	3809162CE01; NB# 0344 3809162DE03; NB# 0344
Safe Sheath CSG (Coronary Sinus Guide)	Class III	N/A	3809162CE01; NB# 0344 3809162DE01; NB# 0344
Worley Advanced CSG (Coronary Sinus Guide)	Class III	N/A	3809162CE01; NB# 0344 3809162DE01; NB# 0344
SafeSheath® Worley LVI (Lateral Vein Introducer)	Class III	N/A	3809162CE01; NB# 0344 3809162DE01; NB# 0344

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Worley Advanced LVI (Lateral Vein Introducer)	Class III	N/A	3809162CE01; NB# 0344 3809162DE01; NB# 0344
Situs LDS 2 (Lateral Vein Introducer	Class III	N/A	3809162CE01; NB# 0344 3809162DE01; NB# 0344
Situs Target (Lateral Vein Introducer)	Class III	N/A	3809162CE01; NB# 0344 3809162DE01; NB# 0344
Transvalvular Insertion Tool (TVI)	Class I device placed on the market in sterile condition	N/A	3809162CE01; NB# 0344
Slitter	Class I device placed on the market in sterile condition	N/A	3809162CE01; NB# 0344
SCOUT Delivery System and Reflector	Class IIb implantable non-WET	N/A	10000334085-PA-NA-NOR; NB# 2460
SCOUT Surgical Guides and SCOUT Handpiece	Class IIa	N/A	10000334085-PA-NA-NOR; NB# 2460
SCOUT Consoles	Class IIa	N/A	10000334085-PA-NA-NOR; NB# 2460
Surfacer Inside Out Access Catheter System	Class III	N/A	31567 Rev. 5; NB# 0459 31568 Rev. 7; NB# 0459
Splittable Sheath Introducer: Prelude Prestige	Class III	N/A	3809162CE02; NB# 03443809162DE05; NB# 0344

Confirmation Letter Revision History

Date	Action
2023/10/12	Initial issue
2024/02/08	Revision to include additional device names omitted in error at initial issue; Performa Device classification updated.