Avanos Medical, Inc.

5405 Windward Parkway

Alpharetta

Georgia

30004 USA

16-May-2024

Notified Body Confirmation Letter

Reference: EU2023-607/839790

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:

Avanos Medical, Inc.
5405 Windward Parkway
Alpharetta, Georgia
30004 USA

SRN Number: US-MF-000016181

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
BALLARD Closed Suction Catheters for Adults with Double Swivel Elbow Manifold 0609038BCSD09634G4	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Closed Suction Catheters for Adults with Double Swivel Elbow Manifold with MDI Port 0609038BCCP09634CG	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Closed Suction Catheters for Adults with Elbow Manifold 0609038BCCE096347Z	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Closed Suction Catheters for Adults with T-Piece Manifold 0609038BCSA09634EV	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Closed Suction Catheters for Neonates/Pediatrics with Elbow Manifold 0609038BNPE09634MF	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Closed Suction Catheters for Neonates/Pediatrics with Neonatal Manifold 0609038BNPN09634R4	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Closed Suction Catheters for Neonates/Pediatrics with Y-Adaptor 0609038BCNP09634JB	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Closed Suction Wet Pak for Adults 0609038BCWP09564P8	Class IIa Article 22.3 Procedure Pack can include the BALLARD Closed Suction Catheter for Adults with Double Swivel Elbow Manifold, BALLARD Closed Suction Catheter for	N/A	CE 711145; 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
	Adults with T-Piece Manifold, which are the highest classifications within the pack. The Procedure Pack can also contain the BALLARD Metered Dose Inhaler (MDI) Adaptor & BALLARD Single Dose Saline Vials.		
BALLARD Metered Dose Inhaler (MDI) Adaptor 0609038BMDI10322DS	Class I device placed on the market in sterile condition	N/A	CE 711145; NB# 2797
BALLARD Oral Care Suction Catheter for Adults 0609038BOCA09564DM	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Oral Care Suction Catheters for Neonates/Pediatrics 0609038BOCS09564LX	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Oral Care Suction Handle 0609038BBSH09564H9	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Oral Care Suction Swab, Angled-Tip 0609038BOSA09564N5	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Oral Care Suction Toothbrush 0609038BOST09564VU	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Oral Care Yankauer 0609038BSCY09564RR	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Ready Care Oral Care Suction Probe 0609038BOSP09564U8	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Single Dose Saline Vials 0609038BSDS09704PL	Class I device placed on the market in sterile condition	N/A	CE 711149; NB# 2797
BALLARD Suction Valve and Y-Adaptor 0609038BSVY095643X	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Turbo-Cleaning Closed Suction Catheter Wet Pak for Adults 0609038BTWP09634Z7	Class IIa Article 22.3 Procedure Pack can include the BALLARD Turbo-Cleaning Closed Suction Catheter for Adults	N/A	CE 711145; 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
	with Double Swivel Elbow Manifold, BALLARD Turbo-Cleaning Closed Suction Catheter for Adults with Double Swivel Elbow Manifold with MDI Port, & BALLARD Turbo-Cleaning Closed Suction Catheter for Adults with T-Piece Manifold, which are the highest classifications within the pack. The Procedure Pack can also contain BALLARD Single Dose Saline Vials.		
BALLARD Turbo-Cleaning Closed Suction Catheters for Adults with Double Swivel Elbow Manifold 0609038BTDS09634QB	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Turbo-Cleaning Closed Suction Catheters for Adults with Double Swivel Elbow Manifold with MDI Port 0609038BDSP09634MK	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Turbo-Cleaning Closed Suction Catheters for Adults with T-Piece Manifold 0609038BTCS09634PS	Class IIa	N/A	CE 711145; NB# 2797
BALLARD Y-Adaptor for Suction Canister 0609038BYSC09564UV	Class IIa	N/A	CE 711145; NB# 2797
Baxter Enteral Cap, ENFit Syringe Compatible, Sterile 0350770NMAF10158FF	Class I device placed on the market in sterile condition	NeoMed* Tip Cap ENFit Syringe Compatible, Sterile	CE 711149; 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
Baxter Enteral Syringes with ENFit Connector, Non-sterile 0350770NSOS00001WB	Class IIa	NeoMed* Oral/Enteral Syringe with ENFit Connector, Non-Sterile NeoMed* Oral/Enteral Syringe, Non-Sterile (Legacy Oral/Enteral Syringes	CE 711145; NB# 2797
Baxter Enteral Syringes with ENFit Connector, Sterile 0350770SCPC8840KB	Class IIa	NeoMed* Oral/Enteral Syringe with ENFit Connector, Sterile NeoMed* Oral/Enteral Syringe, Sterile	CE 711145; NB# 2797
BBraun Enteral Cap, ENFit Syringe Compatible, Sterile 0350770NMAF10158FF	Class I device placed on the market in sterile condition	N/A	CE 711149; NB# 2797
Bbraun Ora/Enteral Syringes with ENFit Connector, Sterile 0350770STES00001V7	Class IIa	N/A	CE 711145; NB# 2797
COOLIEF* Cooled Radiofrequency Fluid Delivery Introducer 0193493CORF00062QF	Class IIa	N/A	CE 711372 & CE 711145; NB# 2797
COOLIEF* Cooled Radiofrequency Fluid Tubing Kit 0193493CRAT00059P8	Class I device placed on the market in sterile condition	N/A	CE 711372; NB# 2797
COOLIEF* Cooled Radiofrequency Kit, Advanced 0193493CRKA00059LT	Class IIb excluding Class IIb implantable non-WET Article 22.3 Procedure Pack includes the COOLIEF* Cooled Radiofrequency Probe, Advanced, which is the highest classification within the pack. The Procedure Pack also contains the COOLIEF* Cooled Radiofrequency Fluid Delivery Introducer & COOLIEF* Cooled Radiofrequency Fluid Tubing Kit.	N/A	CE 711372 & CE 711145; NB# 2797
COOLIEF* Cooled Radiofrequency Probe, Advanced	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; 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
0193493CRFP09528SN			
COOLIEF* Cooled Radiofrequency Sterile Tube Kit 0193493CRST00064YK	Class I device placed on the market in sterile condition	N/A	CE 711372; NB# 2797
COOLIEF* Multi-Cooled Radiofrequency Kit, Advanced 0193493CRKA00059LT	Class IIb excluding Class IIb implantable non-WET Article 22.3 Procedure Pack includes the COOLIEF* Cooled Radiofrequency Probe, Advanced, which is the highest classification within the pack. The Procedure Pack also contains the COOLIEF* Cooled Radiofrequency Fluid Delivery Introducer & COOLIEF* Cooled Radiofrequency Fluid Tubing Kit.	N/A	CE 711372 & CE 711145; NB# 2797
COOLIEF* Quad Pump Unit (QPU) 0193493CQPU00064WS	Class IIb excluding Class IIb implantable non-WET	COOLIEF* Cooled Radiofrequency Peristaltic Pump Unit	CE 711372; NB# 2797
COOLIEF* Radiofrequency Generator (CRG) 0193493PMGE00057SK	Class IIb excluding Class IIb implantable non-WET	COOLIEF* Radiofrequency Pain Management Generator	CE 711372; NB# 2797
COOLIEF* SINERGY* Cooled Radiofrequency Kit, Advanced 0193493SIKA00059SY	Class IIb excluding Class IIb implantable non-WET Article 22.3 Procedure Pack includes the COOLIEF* Cooled Radiofrequency Probe, Advanced, which is the highest classification within the pack. The Procedure Pack also contains the COOLIEF* Cooled Radiofrequency Fluid Delivery Introducer, COOLIEF* SINERGY* Epsilon Ruler, & COOLIEF* Cooled	N/A	CE 711372 & CE 711145; 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
	Radiofrequency Fluid Tubing Kit.		
COOLIEF* SINERGY* Epsilon Ruler 0193493CSER00063QU	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	CE 711372 & CE 711145; NB# 2797
COOLIEF* TRANSDISCAL* Cooled Radiofrequency Introducer 0193493CLTI00062QX	Class IIa	N/A	CE 711372 & CE 711145; NB# 2797
COOLIEF* TRANSDISCAL* Cooled Radiofrequency Probe 0193493CTDP09528SS	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; NB# 2797
COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kit 0193493CRFK00059N8	Class IIb excluding Class IIb implantable non-WET Article 22.3 Procedure Pack includes the COOLIEF* TRANSDISCAL* Cooled Radiofrequency Probe, which is the highest classification within the pack. The Procedure Pack also contains the COOLIEF* TRANSDISCAL* Cooled Radiofrequency Introducer & COOLIEF* Cooled Radiofrequency Fluid Tubing Kit.	N/A	CE 711372 & CE 711145; NB# 2797
CORFLO* 2 Port "Y" Extension Set w/ ENFit Connector 0350770CPYE09654PT	Class IIa	CORFLO* Pediatric/NeoNatal Feeding Tube Extension Set with In-Line Y and ENFit Connectors CORFLO* Pediatric/NeoNatal Feeding Tube Extension Set with ENFit Connectors MIC* Extension Tubing with Threaded Feeding Port and Stepped Connector at Opposite Ends	CE 711145; 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
CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector 0350770CFTN00079GG	Class IIa	CORFLO* Nasogastric/Nasointestinal Feeding Tube CORFLO* Nasogastric/Nasointestinal Feeding Tube with ANTI-IV* Connector	CE 711145; NB# 2797
CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector, Sterile 0350770CNTS00079P9	Class IIa	CORFLO* Nasogastric/Nasointestinal Feeding Tube, Sterile CORFLO* Nasogastric/Nasointestinal Feeding Tube with ANTI-IV* Connector, Sterile	CE 711145; NB# 2797
CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ENFit® Connector 0350770CFTN00079GG	Class IIa	CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ANTI-IV* Connector	CE 711145; NB# 2797
CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ENFit® Connector, Sterile 0350770CNTS00079P9	Class IIa	CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet, Sterile CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ANTI-IV* Connector, Sterile	CE 711145; NB# 2797
CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet with ENFit® Connector, Sterile 0350770CNTS00079P9	Class IIa	CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet, Sterile CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet with ANTI-IV* Connector, Sterile	CE 711145; NB# 2797
CORFLO* Nasointestinal Endoscopically Placed Feeding Tube with ENFit Connector, Non-Sterile	Class IIa	CORFLO* Nasointestinal Endoscopically Placed Feeding Tube, Non-Sterile	CE 711145; 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
0350770CFEP09654BQ			
CORFLO* Nasointestinal Endoscopically Placed Feeding Tube with ENFit Connector, Sterile 0350770EPNS09654R4	Class IIa	N/A	CE 711145; NB# 2797
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Kit with ENFit Connector (PULL) 0350770CPXR18027TN	Class IIb implantable non-WET	N/A	CE 711145; NB# 2797
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Kit with ENFit Connector (PUSH) 0350770CPYC18027N4	Class IIb implantable non-WET	N/A	CE 711145; NB# 2797
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Replacement Feeding Adapter with ENFit Connector 0350770CPEA18027AN	Class IIa	CORFLO* PEG Replacement Feeding Adapter	CE 711145; NB# 2797
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector 0350770CNTN10314M6	Class IIa	CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ANTI-IV* Connector	CE 711145; NB# 2797
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector, Sterile 0350770CNTS10314P7	Class IIa	CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet, Sterile CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ANTI-IV* Connector, Sterile	CE 711145; 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
Enteral Access Dilation System 0350770EFAC023043A	Class IIa	N/A	CE 711145; NB# 2797
FARRELL* Valve Closed Enteral Decompression System with ENFit® Connector 0350770FARL04100DL	Class IIa	FARRELL* Valve Closed Enteral Decompression System (CORPAK Farrell Bag System)	CE 711145; NB# 2797
Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners 0350770IKIT05002LC	Class III	N/A	CE 621871 & CE 711145; NB# 2797
Introducer Kit for Gastrostomy Feeding Tube 0350770IKIT05001aYP	Class III Article 22.3 Procedure Pack includes the Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners, which is the highest classification within the pack. The Procedure Pack also contains the Enteral Access Dilation System & the MIC-KEY* Over-the-Wire Stoma Measuring Device.	N/A	CE 621871 & CE 711145; NB# 2797
Introducer Kit for Jejunal / Gastric-Jejunal Feeding Tube 0350770IKIT05001aYP	Class III Article 22.3 Procedure Pack includes the Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners, which is the highest classification within the pack. The Procedure Pack also contains the Enteral Access Dilation System & the MIC-KEY* Over-the-Wire Stoma Measuring Device.	N/A	CE 621871 & CE 711145; NB# 2797
Introducer Kit for Jejunal/Gastric Feeding Tube 0350770IKIT05001aYP	Class III Article 22.3 Procedure Pack includes the Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners, which is the highest classification within the pack.	N/A	CE 621871 & CE 711145; 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
	The Procedure Pack also contains the Enteral Access Dilation System & the MIC-KEY* Over-the-Wire Stoma Measuring Device.		
Laparoscopic Introducer Kit for Gastrostomy Feeding Tube 0350770IKIT05001aYP	Class III Article 22.3 Procedure Pack includes the Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners, which is the highest classification within the pack. The Procedure Pack also contains the Enteral Access Dilation System & the MIC-KEY* Over-the-Wire Stoma Measuring Device.	N/A	CE 621871 & CE 711145; NB# 2797
Laparoscopic Introducer Kit for Jejunal and Gastric Feeding Tube 0350770IKIT05001aYP	Class III Article 22.3 Procedure Pack includes the Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners, which is the highest classification within the pack. The Procedure Pack also contains the Enteral Access Dilation System & the MIC-KEY* Over-the-Wire Stoma Measuring Device.	N/A	CE 621871 & CE 711145; NB# 2797
Laparoscopic Introducer Kit for Jejunal and Gastric-Jejunal Feeding Tube 0350770IKIT05001aYP	Class III Article 22.3 Procedure Pack includes the Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners, which is the highest classification within the pack. The Procedure Pack also contains the Enteral Access Dilation System & the MIC-KEY* Over-the-Wire Stoma Measuring Device.	N/A	CE 621871 & CE 711145; 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
MIC* Bolus Gastrostomy Feeding Tube with ENFit® Connector 0350770GAFT01903BY	Class IIb excluding Class IIb implantable non-WET	MIC* Bolus Gastrostomy Feeding Tube	CE 711145; NB# 2797
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement 0350770JAFT02001CT	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711145; NB# 2797
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical Placement 0350770JAFT02002CV	Class IIb excluding Class IIb implantable non-WET	Transgastric-Jejunal Feeding Tube Kit MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors MIC* Gastro-Enteric Feeding Tubes	CE 711145; NB# 2797
MIC* Gastrostomy Feeding Tube with ENFit® Connectors 0350770GAFT01902BW	Class IIb excluding Class IIb implantable non-WET	MIC* Gastrostomy Feeding Tube	CE 711145; NB# 2797
MIC* Jejunal Feeding Tube with ENFit® Connector 0350770JAFT02002CV	Class IIb excluding Class IIb implantable non-WET	MIC* Jejunal Feeding Tube	CE 711145; NB# 2797
MIC* PEG Replacement Feeding Adapter with ENFit® Connectors 0350770GAFT01901BU	Class IIa	MIC* PEG Replacement Feeding Adapter MIC* PEG Replacement Adapter	CE 711145; NB# 2797
MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - PULL 0350770IPKS01802QC	Class IIb implantable non-WET	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit PULL	CE 711145; NB# 2797
MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - PUSH OTW 0350770IPKS01801QA	Class IIb implantable non-WET	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit OTW	CE 711145; NB# 2797
MIC-KEY* Over-the-Wire Stoma Measuring Device 0350770MSMD09537RU	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	CE 711149; 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
MIC-KEY* Bolus Feed Extension Set with ENFit® Connector 0350770ENCC09537BE	Class IIa	MIC-KEY* Bolus Feed Extension Set with Cath Tip, SECUR-LOK* Straight Connector and Clamp MIC-KEY* Bolus Extension Set with Cath Tip, SECUR-LOK* Right Angle Connector and Clamp	CE 711145; NB# 2797
MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors 0350770YENC09537SA	Class IIa	MIC-KEY* Continuous Feed Extension Set with SECUR-LOK* Right Angle Connector and 2 Port "Y" and Clamp MIC-KEY* Threaded Extension Set, SECUR-LOK* Right Angle Connector and Clamp	CE 711145; NB# 2797
MIC-KEY* Gastric-Jejunal Feeding Tube Kit with Extension Sets ENFiT 0350770JAFT02001CT	Class IIb excluding Class IIb implantable non-WET	MIC-KEY* Gastric-Jejunal Feeding Tube Kit Endoscopic / Radiologic Placement	CE 711145; NB# 2797
MIC-KEY* Gastrostomy Feeding Tube, Extension Sets with ENFit® Connectors 0350770GAFT01901BU	Class IIb excluding Class IIb implantable non-WET Article 22.3 Procedure Pack includes the MIC-KEY* Gastrostomy Feeding Tube, Low-Profile, which is the highest classification within the pack. The Procedure Pack also contains the MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors & the MIC-KEY* Bolus Feed Extension Set with ENFit® Connector.	MIC-KEY* Gastrostomy Feeding Tube, Extension Sets	CE 711145; NB# 2797
MIC-KEY* Gastrostomy Feeding Tube, Low-Profile 0350770GAFT01901BU	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711145; NB# 2797
MIC-KEY* Jejunal Feeding Tube Kit, Extension Sets with ENFit® Connectors 0350770JAFT02001CT	Class IIb excluding Class IIb implantable non-WET	MIC-KEY* Jejunal Feeding Tube, Low-Profile	CE 711145; NB# 2797
MIC-KEY* Medication Extension Set with ENFit® Connectors, SECUR-LOK*	Class IIa	N/A	CE 711145; 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
Right Angle Connector, 2 Port "Y" ENFit® Connectors 0350770ESRA09537MJ			
MIC-KEY* SF Bolus Feed Extension Set with ENFit Connectors 0350770EZBS09537QH	Class IIa	N/A	CE 711145; NB# 2797
MIC-KEY* SF Continuous Feed Extension Set with ENFit Connectors 0350770EZCF09537KR	Class IIa	MIC-KEY* SF Single Port Extension Set with ENFit Connector, Secure	CE 711145; NB# 2797
MIC-KEY* Single Port Feed Extension Set with ENFit® Connector, SECUR-LOK* Right Angle Connector and Bolus ENFit® Connector and Clamp 0350770SPES09537W8	Class IIa	N/A	CE 711145; NB# 2797
NeoMed Reusable Oral/Enteral Syringe with ENFit Connector - single syringes and bulk packaged 0350770SSUS095368J	Class IIa	NeoMed* Reusable Oral/Enteral Syringe with ENFit Connector, Non-Sterile	CE 711145; NB# 2797
Nitinol Radiofrequency Probe, Curved 0193493SRFP000583S	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; NB# 2797
Nitinol Radiofrequency Probe, Straight 0193493SRFP000583S	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; NB# 2797
Radiofrequency Cannula, Curved Sharp 0193493STRF000626Z	Class IIa	N/A	CE 711372 & CE 711145; NB# 2797
Radiofrequency Cannula, Straight Sharp 0193493STRF000626Z	Class IIa	N/A	CE 711372 & CE 711145; NB# 2797
Radiofrequency Probe, Curved 0193493SRFP000583S	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; NB# 2797
Radiofrequency Probe, Curved – Single Use 0193493SRFP000583S	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; NB# 2797
Radiofrequency Probe, Straight 0193493SRFP000583S	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; NB# 2797
Radiofrequency Probe, Straight – Single Use 0193493SRFP000583S	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711372; 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
Radiopaque Radiofrequency Cannula, Curved Blunt 0193493STRF000626Z	Class IIa	N/A	CE 711372 & CE 711145; NB# 2797
Radiopaque Radiofrequency Cannula, Curved Sharp 0193493STRF000626Z	Class IIa	N/A	CE 711372 & CE 711145; NB# 2797
Radiopaque Radiofrequency Cannula, Straight Sharp 0193493STRF000626Z	Class IIa	N/A	CE 711372 & CE 711145; NB# 2797
COOLIEF* Multi-Cooled RF Therapy Cable 0193493GENE00061JS	Class IIb excluding Class IIb implantable non-WET	COOLIEF* Multi-Cooled Radiofrequency Module	N/A - Device did not require a Notified Body certificate under Directives
COOLIEF* Multi-RF Therapy Cable 0193493GENE00061JS	Class IIb excluding Class IIb implantable non-WET	COOLIEF* Multi-Radiofrequency Module	N/A - Device did not require a Notified Body certificate under Directives
COOLIEF* TRANSDISCAL* Radiofrequency Therapy Cable 0193493GENE00061JS	Class IIb excluding Class IIb implantable non-WET	COOLIEF* TRANSDISCAL* Cooled Radiofrequency Y-Connector Cable	N/A - Device did not require a Notified Body certificate under Directives
CORTRAK* 2 Enteral Access System 0350770CEAS082018Q	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/05/16	Initial issue