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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Avanos Medical, Inc.
Manufacturer address and contact details	5405 Windward Parkway Alpharetta, Georgia (GA) 30004 United States of America Telephone Number: (844)428-2667
Single Registration Number (SRN) (if available)	US-MF-000016181

Authorised Representative name (if applicable)	Avanos Medical Belgium BV
Authorised Representative address and contact details	Leonardo Da Vincilaan 1 1930 Zaventem Belgium
Single Registration Number (SRN) (if available)	BE-AR-000002191

Notified body name (if applicable)	BSi ☒ See attached schedule
Notified body number (if applicable)	2797 ☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 711145 CE 711372 CE 711149 CE 621871 ☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-5-24 ☒See attached schedule
End date of extended validity/transition period	31 December 2027 & 31 December 2028 ☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

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☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name:

Avanos Medical Inc.

Location & Date:

5405 Windward Parkway

Alpharetta, Georgia (GA) 30004

United States of America

Date: 17 May 2024

Signature,



Edward Sanchez,
Principal Regulatory Affairs
edward.sanchez@avanos.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
BALLARD Closed Suction Catheters for Adults with Double Swivel Elbow Manifold	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Closed Suction Catheters for Adults with Double Swivel Elbow Manifold with MDI Port	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Closed Suction Catheters for Adults with Elbow Manifold	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Closed Suction Catheters for Adults with T-Piece Manifold	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Closed Suction Catheters for Neonates/Pediatrics with Elbow Manifold	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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BALLARD Closed Suction Catheters for Neonates/Pediatrics with Neonatal Manifold	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Closed Suction Catheters for Neonates/Pediatrics with Y-Adaptor	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Closed Suction Wet Pak for Adults	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Metered Dose Inhaler (MDI) Adaptor	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Oral Care Suction Catheter for Adults	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Oral Care Suction Catheters for Neonates/Pediatrics	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Oral Care Suction Handle	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Oral Care Suction Swab, Angled-Tip	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Oral Care Suction Toothbrush	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Oral Care Yankauer	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Ready Care Oral Care Suction Probe	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR

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						and does not require a substitute.
BALLARD Single Dose Saline Vials	CE 711149	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Suction Valve and Y-Adaptor	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Turbo-Cleaning Closed Suction Catheter Wet Pak for Adults	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Turbo-Cleaning Closed Suction Catheters for Adults with Double Swivel Elbow Manifold	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Turbo-Cleaning Closed Suction Catheters for Adults with Double Swivel Elbow Manifold with MDI Port	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Turbo-Cleaning Closed Suction Catheters for Adults with T-Piece Manifold	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Y-Adaptor for Suction Canister	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Baxter Enteral Cap, ENFit Syringe Compatible, Sterile	CE 711149	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Baxter Enteral Syringes with ENFit Connector, Non-sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Baxter Enteral Syringes with ENFit Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.

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BBraun Enteral Cap, ENFit Syringe Compatible, Sterile	CE 711149	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BBraun Ora/Enteral Syringes with ENFit Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Cooled Radiofrequency Fluid Delivery Introducer	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Cooled Radiofrequency Fluid Tubing Kit	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Cooled Radiofrequency Kit, Advanced	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Cooled Radiofrequency Probe, Advanced	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Cooled Radiofrequency Sterile Tube Kit	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Multi-Cooled Radiofrequency Kit, Advanced	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Quad Pump Unit (QPU)	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* Radiofrequency Generator	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* SINERGY* Cooled Radiofrequency Kit, Advanced	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR

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						and does not require a substitute.
COOLIEF* SINERGY* Epsilon Ruler	CE 711372 CE 711149	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* TRANSDISCAL* Cooled Radiofrequency Introducer	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* TRANSDISCAL* Cooled Radiofrequency Probe	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kit	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* 2-Port Y Extension Set with ENFit® Connectors	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ENFit® Connector	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ENFit® Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.

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CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet with ENFit® Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Nasointestinal Endoscopically Placed Feeding Tube with ENFit® Connector, Non-Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Nasointestinal Endoscopically Placed Feeding Tube with ENFit® Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Kit with ENFit Connector (PULL)	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Kit with ENFit Connector (PUSH)	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORFLO* Percutaneous Endoscopic Gastrostomy (PEG) Replacement Feeding Adapter with ENFit® Connector	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.

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Transmitting Stylet with ENFit® Connector, Sterile						
Enteral Access Dilation System	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
FARRELL* Valve Closed Enteral Decompression System with ENFit® Connector	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
Gastrointestinal Anchor Set, SAF-T-PEXY* T-Fasteners	CE 621871 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Introducer Kit for Gastrostomy Feeding Tube	CE 621871 CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Introducer Kit for Jejunal / Gastric-Jejunal Feeding Tube	CE 621871 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Introducer Kit for Jejunal/Gastric Feeding Tube	CE 621871 CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Laparoscopic Introducer Kit for Gastrostomy Feeding Tube	CE 621871 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Laparoscopic Introducer Kit for Jejunal and Gastric Feeding Tube	CE 621871 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Laparoscopic Introducer Kit for Jejunal and Gastric-Jejunal Feeding Tube	CE 621871 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2027	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
MIC* Bolus Gastrostomy Feeding Tube with ENFit® Connector	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute

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MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Endoscopic/Radiologic Placement	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical Placement	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC* Gastrostomy Feeding Tube with ENFit® Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC* Jejunal Feeding Tube with ENFit® Connector	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC* PEG Replacement Feeding Adapter with ENFit® Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors – PULL	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2027	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - PUSH OTW	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2027	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* Over-the-Wire Stoma Measuring Device	CE 711149	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
MIC-KEY* Bolus Feed Extension Set with ENFit® Connector	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* Gastric-Jejunal Feeding Tube Kit with Extension Sets ENFiT	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR

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						and does not require a substitute
MIC-KEY* Gastrostomy Feeding Tube, Extension Sets with ENFit® Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute (Article 22.3 Systems and Procedure Packs)
MIC-KEY* Gastrostomy Feeding Tube, Low-Profile	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* Jejunal Feeding Tube Kit, Extension Sets with ENFit® Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* Medication Extension Set with ENFit® Connectors, SECUR-LOK* Right Angle Connector, 2 Port "Y" ENFit® Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* SF Bolus Feed Extension Set with ENFit Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* SF Continuous Feed Extension Set with ENFit Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
MIC-KEY* Single Port Feed Extension Set with ENFit® Connector, SECUR-LOK* Right Angle Connector and Bolus ENFit® Connector and Clamp	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	Not applicable, device will undergo assessment to MDR and does not require a substitute
NeoMed Reusable Oral/Enteral Syringe with ENFit Connector - single syringes and bulk packaged	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Nitinol Radiofrequency Probe, Curved	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.

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Nitinol Radiofrequency Probe, Straight	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiofrequency Cannula, Curved Sharp	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiofrequency Cannula, Straight Sharp	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiofrequency Probe, Curved	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiofrequency Probe, Curved – Single Use	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiofrequency Probe, Straight	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiofrequency Probe, Straight – Single Use	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiopaque Radiofrequency Cannula, Curved Blunt	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiopaque Radiofrequency Cannula, Curved Sharp	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
Radiopaque Radiofrequency Cannula, Straight Sharp	CE 711372 CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
BALLARD Oral Care Kits	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Not applicable, Device will undergo assessment to MDR

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						and does not require a substitute.
Corgrip* Nasogastric/Nasointestinal Feeding Tube Retention System	CE 711145 CE 621870	2024-05-26	BSI 2797	BSI 2782	31 December 2028	Not applicable, Device will undergo assessment to MDR and does not require a substitute.
MIC-KEY* Continuous Feed Extension Set with SECUR-LOK* Right Angle Connector and 2 Port "Y" and Clamp	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors is the substitute device for legacy product
MIC-KEY* Threaded Extension Set, SECUR-LOK* Right Angle Connector and Clamp	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors is the substitute device for legacy product
MIC-KEY* Bolus Feed Extension Set with Cath Tip, SECUR-LOK* Straight Connector and Clamp	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* Bolus Feed Extension Set with ENFit® Connector is the substitute device for legacy product
MIC-KEY* Bolus Extension Set with Cath Tip, SECUR-LOK* Right Angle Connector and Clamp	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* Bolus Feed Extension Set with ENFit® Connector is the substitute device for legacy product
MIC-KEY* SF Single Port Extension Set with ENFit Connector, Secure	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* SF Continuous Feed Extension Set with ENFit Connectors is the substitute device for legacy product
MIC-KEY* Gastrostomy Feeding Tube, Extension Sets	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* Gastrostomy Feeding Tube, Extension Sets with ENFit® Connectors is substitute kit for legacy product
MIC* Gastrostomy Feeding Tube	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Gastrostomy Feeding Tube with ENFit® Connectors is the substitute device for legacy product
MIC* Bolus Gastrostomy Feeding Tube	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Bolus Gastrostomy Feeding Tube with ENFit® Connector is the substitute device for legacy product
Transgastric-Jejunal Feeding Tube Kit	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical

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						Placement is the substitute device for legacy product
MIC* Gastro-Enteric Feeding Tube with ENFit® Connectors	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical Placement is the substitute device for legacy product
MIC* Gastro-Enteric Feeding Tubes	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Gastric-Jejunal Feeding Tube Kit with ENFit® Connector - Surgical Placement is the substitute device for legacy product
MIC-KEY* Gastric-Jejunal Feeding Tube Kit Endoscopic / Radiologic Placement	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* Gastric-Jejunal Feeding Tube Kit with Extension Sets ENFiT is the substitute device for legacy product
MIC* Percutaneous Endoscopic Gastrostomy PEG Kit OTW	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors - PUSH OTW is the substitute device for legacy product.
MIC* Percutaneous Endoscopic Gastrostomy PEG Kit PULL	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Percutaneous Endoscopic Gastrostomy PEG Kit with ENFit® Connectors – PULL is the substitute device for legacy product
MIC* PEG Replacement Feeding Adapter	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* PEG Replacement Feeding Adapter with ENFit® Connectors is the substitute device for legacy product
MIC* PEG Replacement Adapter	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* PEG Replacement Feeding Adapter with ENFit® Connectors is the substitute device for legacy product
FARRELL* Valve Closed Enteral Decompression System (CORPAK Farrell Bag System)	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	FARRELL* Valve Closed Enteral Decompression System with ENFit® Connector is the substitute device for legacy product
MIC-KEY* Jejunal Feeding Tube, Low-Profile	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC-KEY* Jejunal Feeding Tube Kit, Extension Sets with

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						ENFit® Connectors is the substitute device for legacy product
MIC* Jejunal Feeding Tube	CE 711145	2024-05-24	BSI 2797	BSI 2797	31 December 2028	MIC* Jejunal Feeding Tube with ENFit® Connector is the substitute device for legacy product
CORFLO* Pediatric/NeoNatal Feeding Tube Extension Set with In-Line Y and ENFit Connectors	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	Has substitute, see below. CORFLO* 2-Port Y Extension Set with ENFit® Connectors is the substitute device for legacy product.
CORFLO* Pediatric/NeoNatal Feeding Tube Extension Set with ENFit Connectors	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* 2-Port Y Extension Set with ENFit® Connectors is the substitute device for legacy product.
MIC* Extension Tubing with Threaded Feeding Port and Stepped Connector at Opposite Ends	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* 2-Port Y Extension Set with ENFit® Connectors is the substitute device for legacy product.
CORFLO* Nasointestinal Endoscopically Placed Feeding Tube, Non-Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasointestinal Endoscopically Placed Feeding Tube with ENFit® Connector, Non-Sterile is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ENFit® Connector is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ENFit® Connector, Sterile is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal

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Tube with Stylet with ANTI-IV* Connector						Feeding Tube with Stylet with ENFit® Connector is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ANTI-IV* Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Feeding Tube with Stylet with ENFit® Connector, Sterile is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding Tube	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding Tube, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector, Sterile is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with ANTI-IV* Connector	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Feeding Tube with ANTI-IV* Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Feeding Tube with ENFit® Connector, Sterile is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet, Sterile	CE 711145	2024-05-26	BSI 297	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet with ENFit® Connector, Sterile is the substitute device for legacy product.
CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet with ANTI-IV* Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* Nasogastric/Nasointestinal Pediatric Feeding Tube with Stylet with ENFit® Connector,

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						Sterile is the substitute device for legacy product.
CORFLO* PEG Replacement Feeding Adapter	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORFLO* PEG Replacement Feeding Adapter with ENFit® Connector is the substitute device for legacy product.
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector is the substitute device for legacy product.
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ANTI-IV* Connector	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector is the substitute device for legacy product.
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector, Sterile is the substitute device for legacy product.
CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ANTI-IV* Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31December 2028	CORTRAK* 2 Nasogastric/Nasointestinal Feeding Tube with Electromagnetic Transmitting Stylet with ENFit® Connector, Sterile is the substitute device for legacy product.
COOLIEF* Radiofrequency Pain Management Generator	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	COOLIEF* Radiofrequency Generator is the substitute device for legacy product.
COOLIEF* Cooled Radiofrequency Peristaltic Pump Unit	CE 711372	2024-05-26	BSI 2797	BSI 2797	31 December 2028	COOLIEF* Quad Pump Unit is the substitute device for legacy product.

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NeoMed* Oral/Enteral Syringe, Non-Sterile (Legacy Oral/Enteral Syringes	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Baxter Enteral Syringes with ENFit Connector, Non-sterile
NeoMed* Oral/Enteral Syringe with ENFit Connector, Non-Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Baxter Enteral Syringes with ENFit Connector, Non-sterile
NeoMed* Oral/Enteral Syringe with ENFit Connector, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Baxter Enteral Syringes with ENFit Connector, Sterile
NeoMed* Oral/Enteral Syringe, Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Baxter Enteral Syringes with ENFit Connector, Sterile
NeoMed* Reusable Oral/Enteral Syringe with ENFit Connector, Non-Sterile	CE 711145	2024-05-26	BSI 2797	BSI 2797	31 December 2028	NeoMed Reusable Oral/Enteral Syringe with ENFit Connector - single syringes and bulk packaged
NeoMed* Tip Cap ENFit Syringe Compatible, Sterile	CE 711149	2024-05-26	BSI 2797	BSI 2797	31 December 2028	Baxter Enteral Cap, ENFit Syringe Compatible, Sterile

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