C.R. Bard, Inc.
8195 Industrial Boulevard
Covington
Georgia
30014
USA

24-May-2024

Notified Body Confirmation Letter
Reference: EU2023-607/717288

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:

C.R. Bard, Inc.
8195 Industrial Boulevard
Covington, Georgia
30014
USA

SRN Number: US-MF-000018892 (Manufacturer) and US-PR-000037901 (Procedure Pack)

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
Temporary Pacing Electrode Catheter, Balloon Bipolar, 110 cm (4F - 5F), BUDI - 0801741GUKZCGKM3D	Class III	Not Applicable	MDD Certificate #1 – CE 607234 and expiry date – Nov. 19, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Temporary Pacing Electrode Catheter, Semi-Floating Bipolar Electrode, 115 cm (4F - 5F) and 125 cm (6F - 7F)	Class III	Not Applicable	MDD Certificate #1 – CE 607234 and expiry date – Nov. 19, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Temporary Pacing Electrode Catheter, NBIH Bipolar Electrode, 100 cm (5F - 6F) and 125 cm (4F - 7F)	Class III	Not Applicable	MDD Certificate #1 – CE 607234 and expiry date – Nov. 19, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Temporary Pacing Electrode Catheter, NBIH Soft-Tip Bipolar Electrode, 100 cm (6F) and 125 cm (6F - 7F)	Class III	Not Applicable	MDD Certificate #1 – CE 607234 and expiry date – Nov. 19, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Temporary Pacing Electrode Catheter, GOETZ Bipolar Electrode, 100 cm (5F - 6F) and 125 cm (5F - 6F)	Class III	Not Applicable	MDD Certificate #1 – CE 607234 and expiry date – Nov. 19, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Temporary Pacing Electrode Catheter, GOETZ Soft-Tip Bipolar Electrode, 100 cm (6F) and 125 cm (6F)	Class III	Not Applicable	MDD Certificate #1 – CE 607234 and expiry date – Nov. 19, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; 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
Temporary Pacing Electrode Catheter, Balloon Bipolar w/ Right Heart Curve, 110 cm (5F)	Class III	Not Applicable	MDD Certificate #1 – CE 607234 and expiry date – Nov. 19, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardex IC Foley Catheter with BactiGuard™ with Silver Coating Standard Length 2-way with Water Syringe, BUDI - 0801741DFCZIYOBS4	Class IIb - Non Implantable	Not Applicable	MDD Certificate #1 – CE 75331 and expiry date – Nov. 03, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardex IC Foley Catheter with BactiGuard™ with Silver Coating Female Length 2-way, BUDI - 0801741DFCZIYOBS4	Class IIb - Non Implantable	Not Applicable	MDD Certificate #1 – CE 75331 and expiry date – Nov. 03, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardex IC Foley Catheter with BactiGuard™ Silver Coating, Standard Length 2-way, BUDI - 0801741DFCZIYOBS4	Class IIb - Non Implantable	Not Applicable	MDD Certificate #1 – CE 75331 and expiry date – Nov. 03, 2023; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardex IC Comprehesive Care Foley Tray (Procedure Packs) with leg bag, Standard Length, BUDI - 0801741QOLRLAYZ6X	Class IIb - Non Implantable Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD Certificate #1 – CE 543673 and expiry date – May 26, 2024; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; 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
Bardex IC Comprehesive Care Foley Tray (Procedure Packs) with leg bag, Female Length, BUDI - 0801741QOLRLAYZ6X	Class IIb - Non Implantable Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD Certificate #1 – CE 543673 and expiry date – May 26, 2024; NB# 2797 MDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay Optima Ureteral Stent with NiCore Guidewire, BUDI: 0801741BYJHMDUVX3	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay Optima Ureteral Stent without guidewire, BUDI: 0801741BYJHMDUVX3	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay Optima Multi-Length Ureteral Stent with NiCore Guidewire, BUDI: 0801741BYJHMDUVX3	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay Optima Multi-Length Ureteral Stent without guidewire, BUDI: 0801741BYJHMDUVX3	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard HydroGlide Guidewires, BUDI: 0801741AHMQVHVUUD	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay Ureteral Stent with NiCore Guidewire, BUDI: 0801741BFTFZQOBTE	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay VersaFit Ureteral Stent with HydroGlide Guidewire, BUDI: 0801741BFTFZQOBTE	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
InLay Ureteral Stent without guidewire, BUDI: 0801741BFTFZQOBTE	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay VersaFit Ureteral Stent with NiCore Guidewire, BUDI: 0801741BFTFZQOBTE	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
InLay VersaFit Ureteral Stent without guidewire, BUDI: 0801741BFTFZQOBTE	Class IIb - Implantable - non-WET	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
X-Force Ureteral Balloon Dilation Catheters, BUDI: 0801741UPZFFUNBAP	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
X-Force Ureteral Balloon Dilation Catheters (w/ Eagle Inflation Device), BUDI: 0801741UPZFFUNBAP	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Proxis Ureteral Access Sheath, BUDI: 0801741GESMGZWMWJ	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard PTFE Coated Latex Foley Catheters (Tiemann, 2-way), BUDI: 0801741PYLDDRPC5G	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard PTFE Coated Latex Foley Catheter (2-way), BUDI: 0801741PYLDDRPC5G	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardia PTFE Foley Catheter Preconnected to Uriplan Bed Bag; Male Length, BUDI: 0801741PYLDDRPC5G	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Silicone Elastomer Coated Foley Catheter (2-way, 10ml balloon), BUDI: 0801741TPABVPLNZR	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardia Silicone Elastomer Coated Foley Catheter (3 way, 30 ml balloon) Male, BUDI: 0801741TPABVPLNZR	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Silicone Elastomer Coated Foley Catheters (2-way), 30ml Balloon, BUDI: 0801741TPABVPLNZR	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
Prostatic Hydrogel Coated Catheters (3-way, Straight Tip), BUDI: 0801741JLRQVWFY73	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheters (2-way, 10 ml balloon), BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheters (3-way, 30 mL balloon, Prefilled/Aquamatic, Standard Length), BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheters (2-way, Prefilled/Aquamatic, Standard Length), BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheter (2-way, Aquafil, Standard Length) with Water Syringe, BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Catheters (2-way, 30 ml balloon), BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheters (2-way, 5ml balloon) Pediatric, BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheters (2-way, 5ml balloon) Female, BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Foley Catheters (3-way, 5cc balloon) , BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheters (2-way, Prefilled/Aquamatic) Female, BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Hydrogel Coated Foley Catheter Preconnected to Uriplan Bed Bag; Standard Length, BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
Biocath Hydrogel Coated Foley Catheter Preconnected to Center Entry Drainage Bag; Male Length, BUDI: 0801741QJLXCBAUZV	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardia Leg Bags, BUDI: 0801741GXYQAOQD8D	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Uriplan Leg Bags, BUDI: 0801741HPCRNSVIYA	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Bard Flip-Flo Catheter Valve, BUDI: 0801741HRKCMRXNXK	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
All-Silicone Foley Catheters (Male, 10 ml balloon), BUDI: 0801741NKZOKBON5X	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
All-Silicone Foley Catheters (30 ml balloon, male), BUDI: 0801741NKZOKBON5X	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
All-Silicone Foley Catheters (5 ml balloon, pediatric), BUDI: 0801741NKZOKBON5X	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Lubri-Sil All Silicone Hydrogel Coated Foley Catheter (2-Way, 10 ml balloon, male), BUDI: 0801741OIMMXCARZC	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Lubri-Sil Aquafil, Hydrogel Coated All Silicone Foley Catheter (10ml balloon, Male), with pre-filled syringe of sterile water , BUDI: 0801741OIMMXCARZC	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Lubri-Sil Aquafil, Hydrogel Coated All-Silicone Foley Catheter (10ml balloon, Female) with pre-filled syringe of sterile water, BUDI: 0801741OIMMXCARZC	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Lubri-Sil All Silicone Hydrogel Coated Foley Catheter	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date

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
(pediatric), BUDI: 0801741OIMMXCARZC			– May 26, 2024; NB # 2797
Lubri-Sil All Silicone Foley Catheter (2-Way, 10ml balloon, female), BUDI: 0801741OIMMXCARZC	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
X-Force Nephrostomy Balloon Dilation Catheter, BUDI: 0801741LSZSFWSUDD	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
X-Force Nephrostomy Balloon Dilation Catheter (w/ Eagle inflation device), BUDI: 0801741LSZSFWSUDD	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Skylite Nitinol Tipless Baskets, BUDI: 0801741BCKOGKFXLP	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Magic3 Go/HydroSil Go Hydrophilic Intermittent Urinary Catheters (Male Length), BUDI: 0801741LDALWURXU9	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Magic3 Go/HydroSil Go Hydrophilic Intermittent Urinary Catheters (Female Length), BUDI: 0801741LDALWURXU9	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Magic3/HydroSil Hydrophilic Coating Intermittent Urinary Catheters (Male Length), BUDI: 0801741EXAUHSRQZS	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Magic3/HydroSil Hydrophilic Coating Intermittent Urinary Catheters (Female Length), BUDI: 0801741EXAUHSRQZS	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Magic3 Go/HydroSil Go Hydrophilic Intermittent Urinary Catheters (Pediatric Length), BUDI: 0801741LGNLQIKQWU	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Magic3/HydroSil Hydrophilic Coated Intermittent Urinary Catheters (Pediatric Length), BUDI: 0801741FTOZIMDE4Y	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Bard 350ml Urine Meter w/2500mL Drainage Bag, BUDI: 0801741FCLYHHAPRP	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; 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
Bard Closed System Center-Entry Urine Drainage Bag, BUDI: 0801741FCLYHHAPRP	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Bardia Bed Bag, BUDI: 0801741FCLYHHAPRP	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Uriplan Bed Bag, BUDI: 0801741GJZLVKJQ3R	Class Is	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; NB # 2797
Bardex Lubricath Foley Catheter, BUDI: 0801741RNDJWTNY5A	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard NiCore Nitinol Guidewires Standard, benston, BUDI: 0801741HFXRCRKBXG	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard NiCore Nitinol Guidewires Stiff, straight, BUDI: 0801741KDZQLDCRYP	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard NiCore Nitinol Guidewires Standard, Angled, BUDI: 0801741QSGINJKL3L	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard NiCore Nitinol Guidewires Stiff, Angled, BUDI: 0801741QWCGSZEW75	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard NiCore Nitinol Guidewires Standard, straight, BUDI: 0801741SIRBYQPG57	Class IIa - Non-Implantable	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardex IC Foley Catheter with BactiGuard™ Silver Coating, 3-way (30cc balloon), BUDI: 0801741LJXZPTCC9A	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	MDD/AIMDD Certificate #1 – CE 75331 and expiry date – Nov. 03, 2023; NB# 2797 MDD/AIMDD Certificate #2 – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard DigniShield Stool Management System, BUDI: 0801741GPZXYERQBJ	Class IIa	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
Lubri-Sil Comprehensive Care Foley Tray, Community; Lubri-Sil Standard Length Hydrogel Coated All-Silicone Foley Catheter Preconnected to Leg Bag (direct inlet, short tube, or long tube), BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Lubri-Sil Comprehensive Care Foley Tray, Hospital; Lubri-Sil Standard Length Hydrogel Coated All-Silicone Foley Catheter Preconnected to Urine Meter, BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Lubri-Sil Comprehensive Care Foley Tray, Hospital; Lubri-Sil Standard Length Hydrogel Coated All-Silicone Foley Catheter Preconnected to Leg Bag (short inlet tube), BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
	Kit Components – Disposable Apron and Disposable Bag.		
Lubri-Sil Comprehensive Care Foley Tray, Hospital; Lubri-Sil Standard Length Hydrogel Coated All-Silicone Foley Catheter Preconnected to Bed Bag, BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardia Comprehensive Care Foley Tray, Hospital; Bardia PTFE Coated Foley Catheter Preconnected to Urine Meter; Standard Length, BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bardia Comprehensive Care Foley Tray, Hospital; Bardia PTFE Coated Foley Catheter Preconnected to Leg Bag; Standard Length, BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
	Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.		
Bardia Comprehensive Care Foley Tray, Hospital; Bardia PTFE Coated Foley Catheter Preconnected to Bed Bag; Standard Length, BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Comprehensive Care Foley Tray, Community; Biocath Standard Length Hydrogel Coated Foley Catheter Preconnected to Leg Bag (direct inlet, short tube, or long tube), BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Comprehensive Care Foley Tray, Community; Biocath Female Length Hydrogel Coated Foley Catheter Preconnected to Leg Bag (direct inlet, short tube, or long tube), BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
	Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.		
Biocath Comprehensive Care Foley Tray, Hospital; Biocath Standard Length Hydrogel Coated Foley Catheter Preconnected to Urine Meter, BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Comprehensive Care Foley Tray, Hospital; Biocath Standard Length Hydrogel Coated Foley Catheter Preconnected to Leg Bag (Short inlet tube), BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Biocath Comprehensive Care Foley Tray, Hospital; Biocath Standard Length Hydrogel Coated Foley Catheter Preconnected to Bed Bag, BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; 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
	Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.		
Lubri-Sil Comprehensive Care Foley Tray, Community; Lubri-Sil Female Length Hydrogel Coated All-Silicone Foley Catheter Preconnected to Leg Bag (direct inlet, short tube, or long tube), BUDI: 0801741QDEHEGITQ9	Article 22.3 Systems and Procedure Packs Procedure Pack includes the foley catheter which is the highest classification within the pack. The Procedure Pack can contain variations of the following: Sterile Kit Components – Leg Straps, Leg Bags, Skin Prep Pad, Water Syringes, Lube Syringe. Non-Sterile Kit Components – Statlock Foley Stabilization, Gauze, Empty Syringes, Fenestrated Drape, Gloves, Underpad. Non-Medical Kit Components – Disposable Apron and Disposable Bag.	Not Applicable	MDD/AIMDD Certificate – CE 00931 and expiry date – May 26, 2024; NB # 2797
Bard Ellik Evacuator, BUDI: 0801741KFSGANOZU9	Class I device placed on the market in sterile condition	Not Applicable	MDD/AIMDD Certificate – CE 515494 and expiry date – May 26, 2024; 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
N/A	Choose an item.	N/A	N/A

Confirmation Letter Revision History

Date (YYYY/MM/DD)	Action
2023/11/01	Initial issue
2024/04/03	Addition of Devices to Table 1 (Rows 13-89)
2024/05/24	Addition of Ellik Device to Table 1 (Row 90)