Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, Utah
84116
USA

December 20, 2023

Notified Body Confirmation Letter

Reference: EU2023-607/752692

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:

Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, Utah 84116
USA

SRN Number (if available): US-MF-000017720

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.,

Luis Martinez

BSI Scheme Manager

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
PowerLoc Max Power-Injectable Infusion Set	Class IIa	Not Applicable	CE 551333; NB# 2797
MiniLoc Safety Infusion Set	Class IIa	Not Applicable	CE 551333; NB# 2797
Power-Trialysis Short-Term Dialysis Catheter	Class III	Not Applicable	CE 551333; NB# 2797
PowerLoc Safety Infusion Set	Class IIa	Not Applicable	CE 551333; NB# 2797
PowerGlide Pro Midline Catheter	Class IIa	Not Applicable	CE 551333; NB# 2797
PowerGlide Pro Midline Catheter	Class IIa	PowerGlide Pro Midline Catheter with Cue Needle Tracking System	CE 551333; NB# 2797
SafeStep Safety Winged Infusion Set	Class IIa	Not Applicable	CE 551333; NB# 2797
Site~Rite 8 Ultrasound System	Class IIa	Not Applicable	CE 551349; NB# 2797
Site~Rite 8 Ultrasound System	Class IIa	Cue Needle Tracking System Activator	CE 551349; NB# 2797
Site~Rite 8 Ultrasound System	Class IIa	Site~Rite 8 Ultrasound System with Cue Needle Technology	CE 551349; NB# 2797
PowerMidline Catheter	Class IIa	Not Applicable	CE 551333; NB# 2797
PowerPICC Catheter	Class III	Not Applicable	CE 551333; NB# 2797 CE 551344; NB# 2797
PowerPICC Catheter	Class III	PowerPICC SV Catheter	CE 551333; NB# 2797 CE 551344; NB# 2797
PowerPICC Catheter	Class III	PowerPICC FT Catheter	CE 551333; NB# 2797 CE 551344; NB# 2797
PowerPICC Catheter	Class III	PowerPICC HF Catheter	CE 551333; NB# 2797 CE 551344; NB# 2797
PowerPICC SOLO Catheter	Class III	Not Applicable	CE 551333; NB# 2797 CE 551344; NB# 2797
PowerPICC SOLO Catheter	Class III	PowerPICC SOLO FT Catheter	CE 551333; NB# 2797 CE 551344; NB# 2797
PowerPICC SOLO Catheter	Class III	PowerPICC SOLO HF Catheter	CE 551333; NB# 2797 CE 551344; 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
Groshong NXT ClearVue Catheter	Class III	Not Applicable	CE 551333; NB# 2797 CE 551334; NB# 2797
PowerGroshong Catheter	Class III	Not Applicable	CE 551333; NB# 2797 CE 551344; NB# 2797
Provena Midline Catheter	Class IIa	Not Applicable	CE 551333; NB# 2797
Provena Midline Catheter	Class IIa	Groshong Midline Catheter	CE 551333; NB# 2797
MicroEZ Microintroducer	Class IIa	Not Applicable	CE 551333; NB# 2797
Dilators	Class IIa	Not Applicable	CE 551333; NB# 2797
Safety and Non-safety Introducer Needles	Class IIa	Not Applicable	CE 551333; NB# 2797
Guidewires	Class IIa	Not Applicable	CE 551333; NB# 2797
Guidewires	Class III	Not Applicable	CE 551333; NB# 2797 CE 551348; NB# 2797
StatLock Stabilization Devices without Extension Set(s)	Class Is	Not Applicable	CE 551349; 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	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/12/20	Initial issue