BD Switzerland Sàrl

Route de Crassier 17
Business Park Terre-Bonne
Bâtiment A4
1262 Eysins
Switzerland

March 19 2025

Notified Body Confirmation Letter

Reference: EU2023-607/705068 rev.4

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:

BD Switzerland Sàrl

Route de Crassier 17
Business Park Terre-Bonne
Bâtiment A4
1262 Eysins
Switzerland

SRN Number: CH-MF-000026539

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

NB 2797

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
Infusion Administration Set for Gravity	Class I device placed on the market in sterile condition	N/A	CE 506414; NB 2797
VP Infusion Lines	Class IIa	N/A	CE 502238; NB 2797
Texium Closed Male Luer	Class IIa	N/A	CE 502238; NB 2797
Pressure Extension Tubing	Class IIa	N/A	CE 502238; NB 2797
Manifolds, Stopcock, Valve	Class IIa	N/A	CE 502238; NB 2797
Gemini Administration Sets	Class IIa	N/A	CE 502238; NB 2797
Access Device	Class IIa	N/A	CE 502238; NB 2797
SmartSite Needle-free Valve	Class IIa	N/A	CE 502238; NB 2797
Gravity IV Sets, Extension Sets & Components	Class IIa	N/A	CE 502238; NB 2797
GW Infusion Lines	Class IIa	N/A	CE 502238; NB 2797
Extension Sets	Class IIa	N/A	CE 502238; NB 2797
GP Infusion Lines	Class IIa	N/A	CE 502238; NB 2797
MaxPlus™ Needleless Connectors	Class IIa	N/A	CE 502238; NB 2797
MaxPlus Extension Sets	Class IIa	N/A	CE 502238; NB 2797
Texium Needle-Free Syringe	Class IIa	N/A	CE 502238; NB 2797
MaxZero™ Needleless Connector	Class IIa	N/A	CE 502238; NB 2797
MaxZero™ Extension Sets	Class IIa	N/A	CE 502238; NB 2797
Alaris™ GP Volumetric Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ VP Volumetric pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ CC Syringe Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797

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
Alaris™ PK Syringe Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ Gateway Workstation	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
Alaris™ Communication Engine	Class IIb excluding Class IIb implantable non-WET	N/A	CE 502238; NB 2797
BD Alaris neXus and Plus Editor	Class IIb excluding Class IIb implantable non-WET	Alaris™ Editors	CE 502238; NB 2797
BD Q-Syte Devices	Class IIa	N/A	CE 01738; NB 2797
BD Q-Syte™ Vial Access Adapter	Class I device placed on the market in sterile condition	N/A	CE 01738; NB 2797
BD Vial/Bag Access Devices	Class I device placed on the market in sterile condition	N/A	CE 506414; NB 2797
Infusion Administration Set for Gravity	Class IIa	N/A	CE 502238; NB 2797
Alaris GP Volumetric Pump Sets	Class IIa	Alaris SE Infusion Sets	CE 502238; NB 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
2023/11/05	Initial issue
2024/29/02	Addition of BD Q-Syte Devices, BD Q-Syte™ Vial Access Adapter, BD Vial/Bag Access Devices from Table 1.
2024/05/08	Addition of Infusion Administration Set for Gravity from Table 1.
2024/07/30	Addition of Alaris GP Volumetric Pump Sets from Table 1.

By Royal Charter
SUSTAINABLE DEVELOPMENT GOALS

Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

Date	Action
2025/03/19	Addition of MDR Substitute device (BD Alaris neXus and Plus Editor) for the Alaris™ Editors device under MDD from Table 1.

NB 2797