

Sol-Millennium Medical Inc.
315 Shawnee North Dr. Suite 100
Suwanee
GA 30024,
USA

11th April 2024

Notified Body Confirmation Letter
Reference: EU2023-607/820399

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:

Sol-Millennium Medical Inc.
315 Shawnee North Dr. Suite 100
Suwanee
GA 30024,
USA

SRN Number: US-MF-000010890

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
HYPODERMIC NEEDLE: SOL-M Hypodermic Needle	Class IIa	N/A	Certificate # CE 584545 NB #2797
SAFETY NEEDLE: SOL-CARE Safety Needle	Class IIa	N/A	Certificate # CE 584545 NB #2797
BLUNT FILL NEEDLE: SOL-M Blunt Fill Needle	Class I device placed on the market in sterile condition	N/A	Certificate # CE 584545 NB #2797
BLUNT FILL NEEDLE: SOL-M Blunt Fill Needle with Filter Needle	Class I device placed on the market in sterile condition	N/A	Certificate # CE 584545 NB #2797
SAFETY SYRINGE: SOL-CARE Luer Lock Safety Syringe without Needle	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 NB #2797
SAFETY SYRINGE: SOL-CARE TB Safety Syringe with Fixed Needle	Class IIa	N/A	Certificate # CE 584545 NB #2797
SAFETY SYRINGE: SOL-CARE Insulin Safety Syringe with Fixed Needle (U-100 Insulin Only)	Class IIa	N/A	Certificate # CE 584545 NB #2797
STANDARD SYRINGES: SOL-M Slip Tip Syringe with Exchange Needle (Low Dead Space Syringe and non-Low Dead Space needle)	Class IIa	N/A	Certificate # CE 584545 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
STANDARD SYRINGES: SOL-M Eccentric Tip Syringe without Needle (Bulk, Sterile)	Class IIa	N/A	Certificate # CE 584545 NB #2797
STANDARD SYRINGES: SOL-M Slip Tip Syringe without Needle	Class IIa	N/A	Certificate # CE 584545 NB #2797
STANDARD SYRINGES: SOL-M Slip Tip Syringe without Needle (Bulk, Sterile)	Class IIa	N/A	Certificate # CE 584545 NB #2797
STANDARD SYRINGES: SOL-M Slip Tip Syringe without Needle (Low Dead Space)	Class IIa	N/A	Certificate # CE 584545 NB #2797
STANDARD SYRINGES: SOL-M Luer Lock Syringe without Needle	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 NB #2797
STANDARD SYRINGES: SOL-M Luer Lock Syringe without Needle (Bulk, Sterile)	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 NB #2797
STANDARD SYRINGES: SOL-M Allergy Syringe with Fixed Needle (PE Bag)	Class IIa	N/A	Certificate # CE 584545 NB #2797
PEN NEEDLES: SOL-M Pen Needle	Class IIa	N/A	Certificate # CE 584545 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
ORAL AND IRRIGATION SYRINGES: SOL-M Oral Dispensing Syringe Amber with Tip Cap	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 NB #2797
ORAL AND IRRIGATION SYRINGES: SOL-M Oral Dispensing Syringe Clear with Tip Cap	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 NB #2797
ORAL AND IRRIGATION SYRINGES: SOL-M Oral Dispensing Syringe Purple Plunger with Tip Cap	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 NB #2797
ORAL AND IRRIGATION SYRINGES: SOL-M Catheter Tip Syringe without Needle	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 NB #2797
ORAL AND IRRIGATION SYRINGES: SOL-M Catheter Tip Syringe without Needle (Bulk, Sterile)	Class I device placed on the market in sterile condition Class I device with a measuring function	N/A	Certificate # CE 584545 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
SOL-M Butterfly needle with Adapter	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Samplix Blood Collection Set with Luer Adapter	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-M Butterfly needle with End Luer Cap	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Samplix Blood Collection/Infusion Set	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Sol-Care Safety Blood Collection Needle	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Vacumed Blood Collection Set	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
VACUETTE Safety Winged Set with Luer Adapter	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-CARE Safety Winged Infusion Set	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Vacumed Safety Blood Collection Needle	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-CARE Safety Blood Collection Needle with Pre-attached Holder	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Vacumed Safety Blood Collection Needle with Pre-attached Holder	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123

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
VACUETTE Safety Winged Set and Holder	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-GUARD Safety Pull-Button IV Infusion Set	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-GUARD Safety Pull-Button Blood Collection Set with Luer Adapter	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-GUARD Safety Pull-Button Blood Collection Set with Pre-attached Holder	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-M Luer Adapter	Class I device placed on the market in sterile condition	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Vacumed Luer Adapter	Class I device placed on the market in sterile condition	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Samplix Luer Adapter	Class I device placed on the market in sterile condition	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-M Tube Holder with Luer Lock Adapter	Class I device placed on the market in sterile condition	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-M Blood Transfer Holder	Class I device placed on the market in sterile condition	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SOL-M Multi-Sample Needle	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Vacumed Multi-Sample Needle	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
SAMPLIX Multi Sample Needle	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Sol-Care Safety Multi-Sample Needle	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123

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
Sol-Care Safety Multi-Sample Needle with Pre-attached Holder	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123
Vacumed Safety Multi-Sample Needle with Pre-attached Holder	Class IIa	N/A	Certificate # G1 098579 0004 Rev. 00 NB # 0123

Confirmation Letter Revision History

Date	Action
2024/04/11	Initial issue