

Medical Components, Inc.
1499 Delp Drive
Harleysville, PA 19438
USA
03 Jan. 2024

Notified Body Confirmation Letter
Reference: EU2023-607/701578

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:

Medical Components, Inc.
1499 Delp Drive
Harleysville, PA 19438
USA

SRN Number (if available): US-MF-000008230

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.

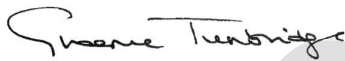
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
Pro-PICC Valved Pro-PICC Jet-PICC PFM-PICC	Class III	Not Applicable	CE 662604; NB No. 2797 CE 616020; NB No. 2797
Dignity, Pro-Fuse and Jet CT Ports	Class III	Not Applicable	CE 662596; NB No. 2797 CE 616020; NB No. 2797
Vascu-PICC	Class III	Not Applicable	CE 662605; NB No. 2797 CE 616020; NB No. 2797
1.9F 2.6F Vascu-PICC	Class III	Not Applicable	CE 662605; NB No. 2797 CE 616020; NB No. 2797
Pro-Line CVC	Class III	Not Applicable	CE 662598; NB No. 2797 CE 616020; NB No. 2797
Vascu-Line CVC	Class III	Not Applicable	CE 662598; NB No. 2797 CE 616020; NB No. 2797
CT Midline/Arch-Flo	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 616020; NB No. 2797
Duo-Flow Duo-Jet Nikkiso Duo-Flow	Class III	Not Applicable	CE 616020; NB No. 2797
Hemo-Cath® ST Nikkiso Hemo-Cath ST	Class III	Not Applicable	CE 616020; NB No. 2797
Duo-Split®	Class III	Not Applicable	CE 616020; NB No. 2797
Duo-Flow® III Duo-Jet® III Nikkiso Duo-Flow® III	Class III	Not Applicable	CE 616020; NB No. 2797
T-3® CT	Class III	Not Applicable	CE 616020; NB No. 2797
Duo-Flow® Soft-Line Duo-Jet® Soft-Line Nikkiso Duo-Flow® Soft-Line®	Class III	Not Applicable	CE 616020; NB No. 2797
Duo-Flow® 400XL	Class III	Not Applicable	CE 616020; NB No. 2797
Duo-Flow® Side x Side Jet Cath® Side x Side Nipro Jet Cath® Side x Side Nikkiso Duo-Flow® Side x Side	Class III	Not Applicable	CE 616020; NB No. 2797
Tri-Flow Jet Tri-Flow	Class III	Not Applicable	CE 616020; NB No. 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
Nipro Tri-Flow Nikkiso Tri-Flow			
Medcomp® Femoral Jet Femoral Nipro Femoral	Class III	Not Applicable	CE 616020; NB No. 2797
Free Flow ST Jet Free Flow ST	Class III	Not Applicable	CE 616020; NB No. 2797
Trio-CT®	Class III	Not Applicable	CE 616020; NB No. 2797
Medcomp® Subclavian Jet Subclavian	Class III	Not Applicable	CE 616020; NB No. 2797
Medcomp® Guidewire Jet Guidewire	Class IIa	Not Applicable	CE 616021; NB No. 2797
Medcomp® Micro-Stick® Introducer Set Jet Micro-Stick® Introducer Set	Class IIa	Not Applicable	CE 616020; NB No. 2797
Medcomp Valved Peelable Introducer Jet Valved Peelable Introducer	Class IIa	Not Applicable	CE 616020; NB No. 2797
Guidewire Introducer Syringe	Class IIa	Not Applicable	CE 616021; NB No. 2797
Statlock® Tesio® Catheter Securement Device Statlock® PICC Plus Catheter Securement Device Statlock® Duo-Jet® II Catheter Securement Device	Class I device placed on the market in sterile condition	Not Applicable	CE 616021; NB No. 2797
Medcomp® Tunneler	Class IIa	Not Applicable	CE 616020; NB No. 2797
Medcomp® Dilator Jet Dilator	Class IIa	Not Applicable	CE 616020; NB No. 2797
Medcomp® Introducer Needle Jet Introducer Needle	Class IIa	Not Applicable	CE 616020; NB No. 2797
Medcomp® End Cap	Class I device placed on the market in sterile condition	Not Applicable	CE 616021; NB No. 2797
"Y" Adaptor	Class IIa	Not Applicable	CE 616020; NB No. 2797
Medcomp® Peelable Introducer	Class IIa	Not Applicable	CE 616020; NB No. 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
Jet Peelable Introducer Introducer Sets			
Pro-Lock™ CT Safety Infusion Set	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 616020; NB No. 2797
I-Series Peritoneal Catheter Jet I-Series Peritoneal Catheter Nipro I-Series Peritoneal Catheter V-Series Peritoneal Catheter Jet V-Series Peritoneal Catheter	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 616020; NB No. 2797
Barbed Luer Lock Adaptor Titanium Luer Adaptor Catheter Stylet Tunneling Stylet	Class IIa	Not Applicable	CE 616020; NB No. 2797
Symetrex® Catheter Symetrex® Catheter with Sideholes	Class III	Not Applicable	CE 653207; NB No. 2797 CE 616020; NB No. 2797
DuraLock 4.0% Catheter Locking Solution	Class III	Not Applicable	CE 616020; NB No. 2797
10F Hemo-Cath Long Term Hemodialysis Catheters	Class III	Not Applicable	CE 663428; NB No. 2797 CE 616020; NB No. 2797
Vascu-Line SL/JET LT CVC Central Venous Catheter	Class III – Implantable	Not Applicable	CE 662601; NB No. 2797 CE 616020; NB No. 2797
Vascu-PICC Taperless, Jet-PICC Taperless	Class III – Implantable	Not Applicable	CE 662605; NB No. 2797 CE 616020; NB No. 2797
Valved Vascu-PICC, Valved Jet-PICC	Class III – Implantable	Not Applicable	CE 662605; NB No. 2797 CE 616020; NB No. 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
2023/10/16	Initial issue
2024/01/03	Addition of the following devices to the list: Vascu-Line SL/JET LT CVC Central Venous Catheter Vascu-PICC Taperless, Jet-PICC Taperless Valved Vascu-PICC, Valved Jet-PICC