

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.

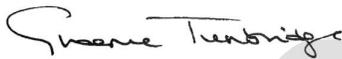
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Pro-PICC Valved Pro-PICC Jet-PICC PFM-PICC</b>	Class III	Not Applicable	CE 662604; NB No. 2797 CE 616020; NB No. 2797
<b>Dignity, Pro-Fuse and Jet CT Ports</b>	Class III	Not Applicable	CE 662596; NB No. 2797 CE 616020; NB No. 2797
<b>Vascu-PICC</b>	Class III	Not Applicable	CE 662605; NB No. 2797 CE 616020; NB No. 2797
<b>1.9F 2.6F Vascu-PICC</b>	Class III	Not Applicable	CE 662605; NB No. 2797 CE 616020; NB No. 2797
<b>Pro-Line CVC</b>	Class III	Not Applicable	CE 662598; NB No. 2797 CE 616020; NB No. 2797
<b>Vascu-Line CVC</b>	Class III	Not Applicable	CE 662598; NB No. 2797 CE 616020; NB No. 2797
<b>CT Midline/Arch-Flo</b>	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 616020; NB No. 2797
<b>Duo-Flow Duo-Jet Nikkiso Duo-Flow</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Hemo-Cath® ST Nikkiso Hemo-Cath ST</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Duo-Split®</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Duo-Flow® III Duo-Jet® III Nikkiso Duo-Flow® III</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>T-3® CT</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Duo-Flow® Soft-Line Duo-Jet® Soft-Line Nikkiso Duo-Flow® Soft-Line®</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Duo-Flow® 400XL</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Duo-Flow® Side x Side Jet Cath® Side x Side Nipro Jet Cath® Side x Side Nikkiso Duo-Flow® Side x Side</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Tri-Flow Jet Tri-Flow</b>	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
<b>Nipro Tri-Flow</b> <b>Nikkiso Tri-Flow</b>			
<b>Medcomp® Femoral Jet Femoral</b> <b>Nipro Femoral</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Free Flow ST</b> <b>Jet Free Flow ST</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Trio-CT®</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Medcomp® Subclavian Jet Subclavian</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>Medcomp® Guidewire Jet Guidewire</b>	Class IIa	Not Applicable	CE 616021; NB No. 2797
<b>Medcomp® Micro-Stick® Introducer Set</b> <b>Jet Micro-Stick® Introducer Set</b>	Class IIa	Not Applicable	CE 616020; NB No. 2797
<b>Medcomp Valved Peelable Introducer</b> <b>Jet Valved Peelable Introducer</b>	Class IIa	Not Applicable	CE 616020; NB No. 2797
<b>Guidewire Introducer Syringe</b>	Class IIa	Not Applicable	CE 616021; NB No. 2797
<b>Statlock® Tesio® Catheter Securement Device</b> <b>Statlock® PICC Plus Catheter Securement Device</b> <b>Statlock® Duo-Jet® II Catheter Securement Device</b>	Class I device placed on the market in sterile condition	Not Applicable	CE 616021; NB No. 2797
<b>Medcomp® Tunneler</b>	Class IIa	Not Applicable	CE 616020; NB No. 2797
<b>Medcomp® Dilator Jet Dilator</b>	Class IIa	Not Applicable	CE 616020; NB No. 2797
<b>Medcomp® Introducer Needle</b> <b>Jet Introducer Needle</b>	Class IIa	Not Applicable	CE 616020; NB No. 2797
<b>Medcomp® End Cap</b>	Class I device placed on the market in sterile condition	Not Applicable	CE 616021; NB No. 2797
<b>"Y" Adaptor</b>	Class IIa	Not Applicable	CE 616020; NB No. 2797
<b>Medcomp® Peelable Introducer</b>	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
<b>Jet Peelable Introducer Introducer Sets</b>			
<b>Pro-Lock™ CT Safety Infusion Set</b>	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 616020; NB No. 2797
<b>I-Series Peritoneal Catheter Jet I-Series Peritoneal Catheter Nipro I-Series Peritoneal Catheter V-Series Peritoneal Catheter Jet V-Series Peritoneal Catheter</b>	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 616020; NB No. 2797
<b>Barbed Luer Lock Adaptor Titanium Luer Adaptor Catheter Stylet Tunneling Stylet</b>	Class IIa	Not Applicable	CE 616020; NB No. 2797
<b>Symetrex® Catheter Symetrex® Catheter with Sideholes</b>	Class III	Not Applicable	CE 653207; NB No. 2797 CE 616020; NB No. 2797
<b>DuraLock 4.0% Catheter Locking Solution</b>	Class III	Not Applicable	CE 616020; NB No. 2797
<b>10F Hemo-Cath Long Term Hemodialysis Catheters</b>	Class III	Not Applicable	CE 663428; NB No. 2797 CE 616020; NB No. 2797
<b>Vascu-Line SL/JET LT CVC Central Venous Catheter</b>	Class III – Implantable	Not Applicable	CE 662601; NB No. 2797 CE 616020; NB No. 2797
<b>Vascu-PICC Taperless, Jet-PICC Taperless</b>	Class III – Implantable	Not Applicable	CE 662605; NB No. 2797 CE 616020; NB No. 2797
<b>Valved Vascu-PICC, Valved Jet-PICC</b>	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