



Medical Components, Inc.
 1499 Delp Drive
 Harleysville, PA 19438, U.S.A.
 P: 215.256.4201
 F: 215.256.1787
 www.medcomp.net

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|--|---|
| Manufacturer name | Medical Components, Inc. |
| Manufacturer address and contact details | 1499 Delp Drive Harleysville, PA 19438 USA Contact: Martina Arno Email: marno@martechmedical.com Phone: 215-859-2589 |
| Single Registration Number (SRN) | US-MF-000008230 |

| | |
|---|--|
| Authorised Representative name | Gerhard Frömel |
| Authorised Representative address and contact details | MPS Medical Product Service GmbH Borngasse 20 35619 Braunfels, Germany Phone: +49 (0) 6442 962073 Fax: +49 (0) 6442 962074 Email: g.froemel@mps-gmbh.eu |
| Single Registration Number (SRN) | DE-AR-000005009 |

| | |
|---|-----------------------------------|
| Notified Body Name | B.S.I. Group the Netherlands B.V. |
| Notified Body Number | 2797 |
| Directive Certificate number(s) to which this confirmation is made | See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity | See attached schedule |
| End date of extended validity/transition period | See attached schedule |

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the **Directive Certificates** listed in the attached schedule, the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed in the attached schedule

- Directive Certificate(s) covering the listed device(s) were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

➤ **Upclassified devices – N/A**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

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



18SEP2023

Ashley Rolfe
Regulatory Affairs Manager
regulatory@medcompnet.com

Date

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

| Identification of the device(s) ¹ (e.g., device name, family/group name device model or catalogue number) | Directive Certificate number(s) to which this confirmation is made (if applicable) | Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable) | Notified Body name and number that issued the Directive Certificate (if applicable) | Notified Body name and number where the MDR application was lodged/contract signed (if applicable) | End date of extended validity / transition period | Substitute Device(s) (if applicable) |
|--|--|--|---|---|--|--|
| Hemo-Cath Long Term Hemodialysis Catheter (10F) | CE 663428 | 16 NOV 2022 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Pro-PICC Valved Pro-PICC Jet-PICC | CE 662604 | 10 OCT 2023 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Dignity, Pro-Fuse and Jet CT Ports | CE 662596 | 11 OCT 2023 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Vascu-PICC Valved Vascu-PICC | CE 662605 | 22 OCT 2023 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Pro-Line CVC Infusion Catheters | CE 662598 | 10 OCT 2023 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Vascu-Line CVC Infusion Catheters | CE 662598 | 10 OCT 2023 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Midline Catheters (CT Midline/Arch-Flo) | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |

¹ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

| | | | | | | |
|---|-----------|-------------|---|---|-------------|-----|
| Short Term Haemodialysis Catheters and Accessories (Duo-Flow/Duo-Jet/Nikkiso Duo-Flow, Hemo-Cath® ST, Nikkiso Hemo-Cath ST, Duo-Split®, Duo-Flow® III, Duo-Jet® III, Nikkiso Duo-Flow® III, T-3® CT, Duo-Flow® Soft-Line, Duo-Jet® Soft-Line®, Duo-Flow® 400XL, Duo-Flow® Side x Side, Jet Cath® Side x Side, Nipro Jet Cath® Side x Side, Nikkiso Duo-Flow® Side x Side, Tri-Flow, Jet Tri-Flow, Nipro Tri-Flow, Nikkiso Tri-Flow, Medcomp® Femoral, Jet Femoral, Nipro Femoral, Free Flow ST, Jet Free Flow ST, Trio-CT®, Medcomp® Subclavian, Jet Subclavian) | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Guidewires | CE 616021 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Micro-Stick Introducer Set | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Introducers | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Syringes (Guidewire Introducer Syringe) | CE 616021 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Anchoring Devices (Statlock® Securement Device) | CE 616021 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Tunnelers | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Dilators and Sheaths | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Needles | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |

| | | | | | | |
|--|-----------|-------------|---|---|-------------|-----|
| Caps and Plugs | CE 616021 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Luers and Adaptors ("Y" Adaptor, Barbed Luer Lock Adaptor Titanium Luer Adaptor) | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Infusion Sets (Pro-Lock™ CT Safety Infusion Set) | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Catheter – Peritoneal Dialysis (I-Series Peritoneal Catheter, Jet I-Series Peritoneal Catheter, Nipro I-Series Peritoneal Catheter, V-Series Peritoneal Catheter, Jet V-Series Peritoneal Catheter) | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Stylets (Catheter Stylet, Tunneling Stylet) | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2028 | N/A |
| Symetrex® Long Term Hemodialysis Catheter | CE 653207 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |
| Catheter Locking Solution (DuraLock 4.0%) | CE 616020 | 26 MAY 2024 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | B.S.I. Group the Netherlands B.V. Notified Body No: 2797 | 31 DEC 2027 | N/A |

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734734 R000

Manufacturer: Medical Components, Inc.

Address:

1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Single Registration Number: US-MF-000008230

EU Authorised Representative: MPS Medical Product Service GmbH

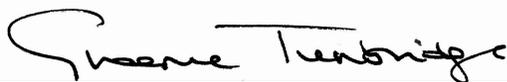
Address:

Borngasse 20
35619 Braunfels
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-11-08**

Current Issue Date: **2023-07-12**

Starting Validity Date: **2023-07-12**

Expiry Date: **2027-11-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734734 R000

Device Schedule: Class III and Class IIb devices

| Class III, Implantable | Intended purpose |
|--|------------------|
| Hemo-Flow, Jet Flow, Nipro Flow Long-Term Hemodialysis Catheter Sets | See MDR 759413 |
| Titan HD Long-Term Hemodialysis Catheter Sets | See MDR 759420 |
| Split Cath III Long-Term Hemodialysis Catheter Sets | See MDR 759428 |
| 10F Tesio, Duo-Jet II, Chronic Twinline Long-Term Hemodialysis Catheter Sets | See MDR 759438 |
| Split Cath Long-Term Hemodialysis Catheter Sets | See MDR 759431 |
| Split Stream Long-Term Hemodialysis Catheter Sets | See MDR 759433 |
| 6.5F Tesio Long-Term Hemodialysis Catheter Sets | See MDR 759439 |
| Canaud Long-Term Hemodialysis Catheter Sets | See MDR 759442 |
| Hemo-Cath LT Long-Term Hemodialysis Catheter Sets | See MDR 759436 |
| DuraLock-C Catheter Lock Solution | See MDR 734736 |

Device Schedule: Class IIa, Custom-made and other devices

| Device(s) | Risk Classification |
|---|---------------------|
| Vascular Access Guidewires, Needles, Tunnelers, Adaptors, Introducers, Dilators | Class IIa |
| Catheter Accessories | Class Is |

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

First Issue Date: **2022-11-08**

Current Issue Date: **2023-07-12**

Starting Validity Date: **2023-07-12**

Expiry Date: **2027-11-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734734 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

| Date | Reference Number | Action |
|------------|------------------|---|
| 2022-11-08 | 3277844 | Issued. |
| 2022-12-19 | 3808456 | Supplemented – Addition of Split-Cath Long-Term Hemodialysis Catheter Sets, Split Stream Long-Term Hemodialysis Catheter Sets, 6.5F Tesio Long-Term Hemodialysis Catheter Sets, Canaud Long-Term Hemodialysis Catheter Sets, and Hemo-Cath LT Long-Term Hemodialysis Catheter Sets devices. |
| Current | 3887150 | Supplemented – Addition of DuraLock-C device. |

First Issue Date: **2022-11-08**

Current Issue Date: **2023-07-12**

Starting Validity Date: **2023-07-12**

Expiry Date: **2027-11-07**

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