EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145252 0001

Report No.: 12031336 018

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo
151-0072 Japan

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-23

Date: 2019-12-23

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

M.Aihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Products included:
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Portable insulin infusion pump
- Portable insulin infusion administration set

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

TERUMO

No.DOC-DQ010- 0245/DOC- DC-0140969
Rev.24

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

RADIFOCUS Introducer II

Product : Catheter Introducer

declare that the above products of **Class IIa** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see Appendix A

署名者:
hiroki sasagawa
署名者名: hiroki sasagawa
署名理由: この文書を承認する
署名時刻： 2024-07-25 | 4:42:35 午後 JST
3F7B1A275BA74182B04CDC2E69B7202D

Tokyo, 2024-07-25
(place and date of issue)

Hiroki Sasagawa
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

□	□	*	□	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) B : Sheath, Dilator, Mini guide wire, (Guide inserter[*2]) C : Sheath, Dilator E : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter[*2]) G : Sheath, Dilator, Mini guide wire, Scalpel[*1] (Guide inserter[*2]) H : Dilator J : Sheath, Dilator, Scalpel[*1] K : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel[*1], (Guide inserter[*2]) L : Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel[*1] M : Sheath, Dilator, Entry needle (SurfloFlash), Scalpel[*1] N : Sheath, Dilator, Mini guide wire, Syringe, Scalpel[*1], (Guide inserter[*2]) P : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter[*2]) Q : Dilator, Mini guide wire, (Guide inserter[*2]) R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter[*2]) S : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) W : Mini guide wire [*1]: not contained in the export specifications [*2]: contained when the mini guide wire has an angled tip or a J tip.

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>5-6</td><td>Sheath Size (w/o hydrophilic polymer coating)
Characters: 40 50 55 60 65 70 75 80 85 90 10 11 00
Size: 4.0 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0 11.0 no sheath
Sheath Size (with hydrophilic polymer coating)
Characters: F4 F5 F6 F7
Size: 4.0 5.0 6.0 7.0</td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>b-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">Standard</td></tr>
<tr><td>a-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>b-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">With adapter</td></tr>
<tr><td>a-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>---</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table>
Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM):
<table>
<tr><th colspan="2" rowspan="2"></th><th colspan="5">Mini guide wire diameter/ Dilator inner diameter</th><th rowspan="2">Type of Surflo</th></tr>
<tr><th>0.018”</th><th>0.021”</th><th>0.025”</th><th>0.035”</th><th>0.038”</th></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>b-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">With adapter</td></tr>
<tr><td>a-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>b-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">Standard</td></tr>
<tr><td>a-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>Metallic Entry Needle improved product 20G×1 2/5”</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table>
</td></tr>
</table>

Character number	Characters & Meaning
8-9	Length of sheath 05 ~: 50 mm ~
10	Type of mini guide wire A: Plastic, Angled B: Plastic, Angled, 4mm of tip cut E: Straight E F: Flex, Angled H: Short tapered, short angle J: Plastic, 3mm J K: Stiff, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight V: Plastic, 1.5mm J-angle Y: Flex, Straight
11	Packaging Q: Tray package (Multi-language) R: Pouch package (Multi-language)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038”, Outer diameter of mini guide wire: 0.035” Z: Entry needle: 20Gx2”→20Gx1 1/4” Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx2”→20Gx1 1/4”, scalpel contained.

Appendix A - List of Code Number Structure

□ □ □ □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11 12

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>1, 2</td><td>Product name
RS: Introducer kit
RM: Introducer kit containing hydrophilic polymer-coated sheath</td></tr>
<tr><td>3</td><td>Destination
+ / ＊: Manufactured by TVC for worldwide excluding Japan</td></tr>
<tr><td>4</td><td>Kit contents
A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel*1, (Guide inserter*2)
B : Sheath, Dilator, Mini guide wire, (Guide inserter*2)
C : Sheath, Dilator
R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter*2)
*1: not contained in the export specification
*2: contained when the mini guide wire has an angled tip or a J tip.</td></tr>
<tr><td>5-6</td><td>Sheath Size (Fr) (w/o hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td></tr>
<tr><td>Size</td><td>4.0</td><td>5.0</td><td>6.0</td><td>7.0</td><td>8.0</td></tr>
</table>
Sheath Size (Fr) (with hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>F5</td><td>F6</td></tr>
<tr><td>Size</td><td>5.0</td><td>6.0</td></tr>
</table></td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)
<table>
<tr><td></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td></td><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td>Type of scalpel and tray</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td>Standard</td></tr>
<tr><td>Entry needle size</td><td>---</td><td>---</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td>Metallic needle size</td><td>Metallic Entry Needle improved product 22G×1 2/5”</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>Metallic Entry Needle improved product 20G×1 2/5”</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td>Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM*)
<table>
<tr><td rowspan="2"></td><td colspan="3">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.021”</td><td>0.025”</td><td>0.035”</td></tr>
<tr><td rowspan="2">Type of scalpel and tray</td><td>---</td><td>G</td><td>---</td><td>With adapter</td></tr>
<tr><td>F</td><td>J</td><td>M</td><td>Standard</td></tr>
<tr><td>Entry needle size</td><td>---</td><td>20G×2”</td><td>---</td><td></td></tr>
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</table></td></tr>
<tr><td>8-9</td><td>Length of sheath
00 : no sheath
05~ : 50mm~ ~</td></tr>
<tr><td>10</td><td>Type of mini guide wire
A: Plastic, Angled
M: Spring, J angled
N: No mini guide wire contained.
P: Spring, Straight
S: Plastic, Straight
H: Short tapered, short angle</td></tr>
<tr><td>11</td><td>Packaging
Q: Tray package (Multi-language #, Chinese)
R: Pouch package (Multi-language #, Chinese)</td></tr>
<tr><td>12</td><td>Reserved
1: With scalpel.
5: Inner diameter of dilator at distal end: 0.038”,
Outer diameter of mini guide wire: 0.035”
Z: Entry needle: 20Gx2”→20Gx1 1/4”
Length of mini guide wire: 80cm→45cm, scalpel contained.
W: Entry needle: 20Gx2” →20Gx1 1/4” , scalpel contained.</td></tr>
</table>

Reference to. TC_CL607_2024-03-06

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	Terumo Corporation
Manufacturer address and contact details	44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, 151-0072, Japan E-Mail: Eudamed_PRRC@terumo.co.jp
Single Registration Number (SRN) (if available)	JP-MF-000017478

Authorised Representative name (if applicable)	Terumo Europe N.V.
Authorised Representative address and contact details	Interleuvenlaan, 40 3001 Leuven, Belgium E-Mail: Koen.Verhaert@terumo-europe.com
Single Registration Number (SRN) (if available)	BE-AR-000001433

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH □ See attached schedule
Notified body number (if applicable)	0197 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	See Schedule of Devices ■ 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.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See Schedule of Devices ■ See attached schedule
End date of extended validity/transition period	See Schedule of Devices ■ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) 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 above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/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

[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

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.

➢ **Upclassified devices**

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.

Reference to. TC_CL607_2024-03-06

Signed for and on behalf of the manufacturer:

Terumo Corporation
Full Company Name

Tokyo , 2024-03-12
Location **Date**

Toshio Nakashima
Print Name

General Manager
Quality Assurance Department
Title

DocuSigned by:
Signer Name: Toshio Nakashima
Signing Reason: I approve this document
Signing Time: 2024-03-12 | 1:48:38 午後 JST
7CB53CAEA6904D2895AEA45B61783210
Legally binding signature

Eudamed_PRRC@terumo.co.jp
Contact Details

Schedule of Devices

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

Identification of the device(s)[3] (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)
Destination (sheath, dilator, valve, dailator retaining clip)	EC Design-Examination Certificate ID 60134974 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60134974 0001 and expiry date;2023-12-08 EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	N/A

[3] 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)

Identification of the device(s)[3] (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)
TERUMO Syringe	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A
SURFLASH	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	Surflash
VERSATUS	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	Versatus

Identification of the device(s)[3] (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)
Heartrail II	EC Design-Examination Certificate ID 60149274 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60149274 0001 and expiry date;2024-05-26 EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	N/A
Blood Bags with Anticoagulant/ Preservation Solution(Leukocyte Removal Filter integrated type)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	N/A

Identification of the device(s)[3] (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)
TERUFLEX Transfer Bags	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	TERUMO Transfer Bags
IMUGARD III-RC (with blood bags)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	IMUGARD III-RC
IMUGARD III-RC (without blood bags)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	IMUGARD III-RC

Identification of the device(s)[3] (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)
RADIFOCUS OPTITORQUE	EC Design-Examination Certificate ID 60149172 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60149172 0001 and expiry date;2024-05-26 EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	N/A
RADIFOCUS ANGIOGRAPHIC CATHETER	EC Design-Examination Certificate ID 60149266 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60149266 0001 and expiry date;2024-05-26 EC Certificate-Full Quality Assurance System	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	N/A

Identification of the device(s)[3] (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)
		HD 60145252 0001 and expiry date;2024-05-26				
TERUFUSION BLOOD ADMINISTRATION SET	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	TERUFUSION Blood Administration Set
FINETOUCH Lancet	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A
MEDISAFE Lancet for FINETOUCH	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A

Identification of the device(s)[3] (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)
Immucise Intradermal Injection System	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	IMMUCISE Intradermal Injection System
Immucise Intradermal Injection needle	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	IMMUCISE Intradermal Injection System
Immucise Syringe	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	IMMUCISE Intradermal Injection System

Identification of the device(s)[3] (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)
Teruflex Blood Bag without Anticoagulant	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	TERUMO Blood Bag without Anticoagulant
Outlook	EC Design-Examination Certificate ID 60148413 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60148413 0001 and expiry date;2024-05-26 EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	OUTLOOK

Identification of the device(s)[3] (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)
Radifocus Glidecath	EC Design-Examination Certificate ID 60148569 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60148569 0001 and expiry date;2024-05-26 EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	RADIFOCUS GLIDECATH
RADIFOCUS GUIDE WIRE M	EC Design-Examination Certificate ID 60156558 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60156558 0001 and expiry date;2024-05-26 EC Certificate-Full Quality Assurance System	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	N/A

Identification of the device(s)[3] (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)
		HD 60145252 0001 and expiry date;2024-05-26				
RADIFOCUS GUIDE WIRE GT with Gold Coil	EC Design-Examination Certificate ID 60156558 0001 EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Design-Examination Certificate ID 60156558 0001 and expiry date;2024-05-26 EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2027-12-31	N/A

Identification of the device(s)[3] (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)
MEDISAFE WITH Main Pump Unit	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	MEDISAFE WITHMain Pump Unit, REF MZ*PP01T
MEDISAFE WITH Cartridge	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	MEDISAFE WITHCartridge, REF MZ*PC10T

Identification of the device(s)[3] (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)
MEDISAFE WITH Remote Control	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	MEDISAFE WITHRemote Control, REF MZ*PR01T
MEDISAFE WITH Filling Device	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	MEDISAFE WITHFilling Device, REF MZ*PF01T

Identification of the device(s)[3] (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)
RADIFOCUS Glidewire Advantage	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	Radifocus Glidewire Advantage
Single Use Guidewire	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A
Glidesheath Slender (sheath, dilator, mini guide wire, entry needle, guide inserter)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	Glidesheath Slender

Identification of the device(s)[3] (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)
RADIFOCUS INTRODUCER II (sheath, dilator, mini guide wire, entry needle, syringe, scalpel and guide inserter)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	RADIFOCUS INTRODUCER II
RADIFOCUS Obturator	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A
RADIFOCUS Vessel Dilator	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A

Identification of the device(s)[3] (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)
RADIFOCUS Haemostasis Valve II	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A
RADIFOCUS Guide Wire M Non-vascular	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A
Outlook Peripheral Use	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A

Identification of the device(s)[3] (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)
Navicross (0.018 inch)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	NaviCross
Navicross (0.035 inch)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	NaviCross
TERUFUSION SS 10	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	TERUFUSION Syringe Pump Type SS3

Identification of the device(s)[3] (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)
TERUFUSION SS 10 TCI	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	TERUFUSION Syringe Pump Type SS3TCI /TERUFUSION Syringe Pump Type SS3OTCI
TERUFUSION LF(TBD)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	TERUFUSION Infusion Pump Type LF3

Identification of the device(s)[3] (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)
TERUFUSION LM(TBD)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	TERUFUSION Infusion Pump Type LM3
MEDISAFE WITH Infusion Set	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	MEDISAFE WITHInfusion Set, REF MZ*PS10T
IMUGARD III-PL (without blood bags)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	IMUGARD III-PL

Identification of the device(s)[3] (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)
IMUGARD III-PL (with blood bags)	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	IMUGARD III-PL
RADIFOCUS Glidewire Advantage Track	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	Radifocus Glidewire Advantage
Tercross	EC Certificate-Full Quality Assurance System HD 60145252 0001	EC Certificate-Full Quality Assurance System HD 60145252 0001 and expiry date;2024-05-26	TÜV Rheinland LGA Products GmbH NB 0197	TÜV Rheinland LGA Products GmbH NB 0197	2028-12-31	N/A

Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date March 06, 2024

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Notified Body Confirmation Letter
Reference. : TC_CL607_2024-03-06

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan
SRN Number: JP-MF-000017478

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 under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD certificate expiry.

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.

- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa

On behalf of the Notified Body

Michiaki Aihara
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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
Destination (sheath, dilator, valve, dailator retaining clip)	Class III	Destination	ID 60134974 0001 (NB#0197) HD 60145252 0001 (NB#0197)
TERUMO Syringe	Class IIa	N/A	HD 60145252 0001 (NB#0197)
SURFLASH	Class IIa	Surflash	HD 60145252 0001 (NB#0197)
VERSATUS	Class IIa	Versatus	HD 60145252 0001 (NB#0197)
Heartrail II	Class III	N/A	ID 60149274 0001 (NB#0197) HD 60145252 0001 (NB#0197)
Blood Bags with Anticoagulant/ Preservation Solution(Leukocyte Removal Filter integrated type)	Class III	N/A	HD 60145252 0001 (NB#0197)
TERUFLEX Transfer Bags	Class IIb	TERUMO Transfer Bags	HD 60145252 0001 (NB#0197)
IMUGARD III-RC (with blood bags)	Class IIb	IMUGARD III-RC	HD 60145252 0001 (NB#0197)
IMUGARD III-RC (without blood bags)	Class IIa	IMUGARD III-RC	HD 60145252 0001 (NB#0197)
RADIFOCUS OPTITORQUE	Class III	N/A	ID 60149172 0001 (NB#0197) HD 60145252 0001 (NB#0197)
RADIFOCUS ANGIOGRAPHIC CATHETER	Class III	N/A	ID 60149266 0001 (NB#0197) HD 60145252 0001 (NB#0197)
TERUFUSION BLOOD ADMINISTRATION SET	Class IIa	TERUFUSION Blood Administration Set	HD 60145252 0001 (NB#0197)
FINETOUCH Lancet	Class IIa	N/A	HD 60145252 0001 (NB#0197)
MEDISAFE Lancet for FINETOUCH	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Immucise Intradermal Injection System	Class IIa	IMMUCISE Intradermal Injection System	HD 60145252 0001 (NB#0197)
Immucise Intradermal Injection needle	Class IIa	IMMUCISE Intradermal Injection System	HD 60145252 0001 (NB#0197)
Immucise Syringe	Class IIa	IMMUCISE Intradermal Injection System	HD 60145252 0001 (NB#0197)
Teruflex Blood Bag without Anticoagulant	Class IIb	TERUMO Blood Bag without Anticoagulant	HD 60145252 0001 (NB#0197)
Outlook	Class III	OUTLOOK	ID 60148413 0001 (NB#0197) HD 60145252 0001 (NB#0197)

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
Radifocus Glidecath	Class III	RADIFOCUS GLIDECATH	ID 60148569 0001 (NB#0197) HD 60145252 0001 (NB#0197)
RADIFOCUS GUIDE WIRE M	Class III	N/A	ID 60156558 0001 (NB#0197) HD 60145252 0001 (NB#0197)
RADIFOCUS GUIDE WIRE GT with Gold Coil	Class III	N/A	ID 60156558 0001 (NB#0197) HD 60145252 0001 (NB#0197)
MEDISAFE WITH Main Pump Unit	Class IIb	MEDISAFE WITH-Main Pump Unit, REF MZ*PP01T	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Cartridge	Class IIb	MEDISAFE WITH-Cartridge, REF MZ*PC10T	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Remote Control	Class IIb	MEDISAFE WITH-Remote Control, REF MZ*PR01T	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Filling Device	Class IIa	MEDISAFE WITH-Filling Device, REF MZ*PF01T	HD 60145252 0001 (NB#0197)
RADIFOCUS Glidewire Advantage	Class IIa	Radifocus Glidewire Advantage	HD 60145252 0001 (NB#0197)
Single Use Guidewire	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Glidesheath Slender (sheath, dilator, mini guide wire, entry needle, guide inserter)	Class IIa	Glidesheath Slender	HD 60145252 0001 (NB#0197)
RADIFOCUS INTRODUCER II (sheath, dilator, mini guide wire, entry needle, syringe, scalpel and guide inserter)	Class IIa	RADIFOCUS INTRODUCER II	HD 60145252 0001 (NB#0197)
RADIFOCUS Obturator	Class IIa	N/A	HD 60145252 0001 (NB#0197)
RADIFOCUS Vessel Dilator	Class IIa	N/A	HD 60145252 0001 (NB#0197)
RADIFOCUS Haemostasis Valve II	Class IIa	N/A	HD 60145252 0001 (NB#0197)
RADIFOCUS Guide Wire M Non-vascular	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Outlook Peripheral Use	Class IIa	N/A	HD 60145252 0001 (NB#0197)
Navicross (0.018 inch)	Class IIa	NaviCross	HD 60145252 0001 (NB#0197)
Navicross (0.035 inch)	Class IIa	NaviCross	HD 60145252 0001 (NB#0197)
TERUFUSION SS 10	Class IIb	TERUFUSION Syringe Pump Type SS3	HD 60145252 0001 (NB#0197)
TERUFUSION SS 10 TCI	Class IIb	TERUFUSION Syringe Pump Type SS3TCI / TERUFUSION Syringe Pump Type SS3OTCI	HD 60145252 0001 (NB#0197)

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
TERUFUSION LF(TBD)	Class IIb	TERUFUSION Infusion Pump Type LF3	HD 60145252 0001 (NB#0197)
TERUFUSION LM(TBD)	Class IIb	TERUFUSION Infusion Pump Type LM3	HD 60145252 0001 (NB#0197)
MEDISAFE WITH Infusion Set	Class IIa	MEDISAFE WITH-Infusion Set, REF MZ*PS10T	HD 60145252 0001 (NB#0197)
IMUGARD III-PL (without blood bags)	Class IIa	IMUGARD III-PL	HD 60145252 0001 (NB#0197)
IMUGARD III-PL (blood bags)	Class IIb	IMUGARD III-PL	HD 60145252 0001 (NB#0197)
RADIFOCUS Glidewire Advantage Track	Class IIa	Radifocus Glidewire Advantage	HD 60145252 0001 (NB#0197)
Tercross	Class IIa	N/A	HD 60145252 0001 (NB#0197)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/12/01	TC_CL607_Destination_2023-12-01	Initial issue
2024/03/01	TC_CL607_2024-03-01	Products addition (44 items)
2024/03/06	TC_CL607_2024-03-06	Add Certificate Reference for IMUGARD III-PL (blood bags)