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	General Manager Quality Assurance Department	Signer Name: Toshio Nakashima Signing Reason: I approve this document Signing Time: 2024-03-12 | 1:48:38 午後 JST 7CB53CAEA6904D2895AFA45B61783210
Print Name	**Title**	**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