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*
- 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 Europe N.V.
Manufacturer address and contact details	Interleuvenlaan 40 3001 Leuven Belgium Mail: koen.verhaert@terumo-europe.com
Single Registration Number (SRN) (if available)	BE-MF-000001434

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH x See attached schedule
Notified body number (if applicable)	0197 x See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	x See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 x See attached schedule
End date of extended validity/transition period	2027-12-31 x 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*
- 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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.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:

  X Expired/expires *after* 20 March 2023:

  X 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.

➢ **Quality Management System (QMS)**

X A QMS in accordance with Article 10(9) MDR is in place.

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

- The device(s) continue to comply with the 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:

TERUMO EUROPE N.V.
Leuven, 25-Apr-2024 | 17:16 CEST

DocuSigned by:

Signer Name: Koen Verhaert
Signing Reason: I approve this document
Signing Time: 25-Apr-2024 | 17:11 CEST
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K.Verhaert, VP Quality, Regulatory & Vigilance
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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)
RADIFOCUS Angiographic Catheter (Angiographic Catheter)	HD 60134707 0001 ID 60149263 0001	2024-05-26	TÜV Rheinland LGA Products GmbH 0197	TÜV Rheinland LGA Products GmbH 0197	2027-12-31	/
RADIFOCUS Glidecath (Angiographic Catheter)	HD 60134707 0001 ID 60148570 0001	2024-05-26	TÜV Rheinland LGA Products GmbH 0197	TÜV Rheinland LGA Products GmbH 0197	2027-12-31	/
RADIFOCUS Optitorque (Angiographic Catheter)	HD 60134707 0001 ID 60149181 0001	2024-05-26	TÜV Rheinland LGA Products GmbH 0197	TÜV Rheinland LGA Products GmbH 0197	2027-12-31	/
Outlook (Angiographic Catheter)	HD 60134707 0001 ID 60148411 0001	2024-05-26	TÜV Rheinland LGA Products GmbH 0197	TÜV Rheinland LGA Products GmbH 0197	2027-12-31	/
RADIFOCUS Guide Wire M (vascular guide wire)	HD 60134707 0001 ID 60156557 0001	2024-05-26	TÜV Rheinland LGA Products GmbH 0197	TÜV Rheinland LGA Products GmbH 0197	2027-12-31	/

[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