



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)	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period	<input checked="" type="checkbox"/> 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 Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.

Expires *after* 20 March 2023:

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

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.

Interleuvenlaan 40, 3001, Belgium

DocuSigned by:

Koen Verhaert



Signer Name: Koen Verhaert
Signing Reason: I approve this document
Signing Time: 22-Nov-2023 | 23:43 CET

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Koen Verhaert (Koen.verhaert@terumo-europe.com)

VP Quality, Regulatory and Vigilance



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)
Ultimaster Tansei Sirolimus eluting coronary stent system	3479GB410191217	27/05/2024	DNV MEDCERT 0482	DNV MEDCERT 0482	31/12/2027	Not applicable
	13090GB411200504	27/05/2024				

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