

EU DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
with Single Registration Number: **JP-MF-000017478**

being the manufacturer of:

TR Band

[PERCUTANEOUS ARTERIAL ACCESS HAEMOSTASIS SYSTEMS]

Intended purpose: The TR Band is intended to be used for temporary hemostasis at the puncture site after catheterization via the radial artery.

Basic UDI-DI: 498735026RF06KL

Related product codes:

Product code	UDI-DI	Manufacturing site
XX*RF06L	04987350779212	Ashitaka factory
	06927675515964	Terumo Medical Products (Hangzhou) CO., LTD.
XX*RF06	04987350766816	Ashitaka factory
	06927675515957	Terumo Medical Products (Hangzhou) CO., LTD.

declare that the above product of **Class I sterile** is in conformity with the applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.7 of the Regulation, relating to the “Conformity assessment based on a quality management system and on assessment of technical documentation” set out in Annex IX, however limited to the aspects relating to establishing, securing and maintaining sterile conditions, and by certification of Annex IX Chapter I & III (EU quality management system certificate number HZ 1485480-1, under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

There is no reference to Common Specifications that have been used within the conformity assessment for Regulation (EU) 2017/745.



Rev. 00
No. DOC- DC-0090250
[Reference to DC-0090250]

Authorised Representative: TERUMO EUROPE N.V. (SRN: BE-AR-000001433)
INTERLEUVENLAAN 40, 3001 LEUVEN, BELGIUM

This EU declaration of conformity is issued under our sole responsibility.

Tokyo , 2023-05-01

(place and date of issue)

A handwritten signature in blue ink, appearing to read "Toshio Nakashima", positioned above a horizontal line.

Toshio Nakashima
General Manager
Quality Assurance
Department
For and on behalf of
TERUMO CORPORATION