



EU DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

with Single Registration Number: **BE-MF-000001434**

being the manufacturer of:

RADIFOCUS™ Introducer II **- Introducer for radial access -**

Intended purpose: The RADIFOCUS Introducer II for radial access is intended to be inserted percutaneously into the radial artery to facilitate the insertion of angiographic, electrode, balloon, or similar catheters

Basic UDI-DI: 5413206TRICE

Related product codes: See Appendix A

declare that the above product of **Class IIa** is in conformity with 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 52.6 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, and by certification of Annex IX.3 (EU quality management system certificate number HZ 1594584-1), 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.

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

Leuven , 2024-11-08

(place and date of issue)

Signed by:
Koen Verhaert
Signer Name: Koen Verhaert
Signing Reason: I approve this document
Signing Time: 08-Nov-2024 | 18:37 CET
7F80D9F0AA864C9092C6E4219E273655

K. Verhaert
VP Quality, Regulatory & Vigilance
For and on behalf of TERUMO EUROPE N.V.



Appendix A – Related product codes

- The product code is composed of maximum 12 digits maximum and explained as follows:

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|--|----------|---|--------------------|--|------|----------------------|----------|--------------|---|----------------------------|----|
| R | T | RADIFOCUS Introducer II for radial access | | | | | | | | | |
| Production site | | - | Terumo Europe N.V. | | | | | | | | |
| Indication of kit composition | | | R | Sheath introducer, Dilator, Spring guide wire and Metallic introducer needle | | | | | | | |
| Size of sheath in Fr | | | 4 | 0 | 4 Fr | | | | | | |
| | | | 5 | 0 | 5 Fr | | | | | | |
| | | | 6 | 0 | 6 Fr | | | | | | |
| | | | 7 | 0 | 7 Fr | | | | | | |
| Dilator I.D., distal tip length (difference of Dilator / sheath assembly), and type of metallic introducer needle | | | | | | Difference in length | | Dilator I.D. | Metallic introducer needle | | |
| | | | | | | A | 25 | 0.018" | 22G x 35 mm | | |
| | | | | | | D | 25 | 0.021" | 21G x 35 mm | | |
| Length of the sheath | | | | | | 0 | 7 | 70 mm | | | |
| | | | | | | 1 | 0 | 100 mm | | | |
| Mini spring guide wire type | | | | | | | | P | Straight, fixed core, uncoated, distal end flexible | | |
| Packaging | | | | | | | | | Q | Tray pack (Multi language) | |
| Special product indication: alphanumeric digit to distinguish from standard items | | | | | | | | | | X | |

- List of product codes

| 4Fr | 5Fr | 6Fr | 7Fr |
|-------------|-------------|-------------|-------------|
| RT-R40A07PQ | RT-R50A07PQ | RT-R60A07PQ | RT-R70D10PQ |
| RT-R40A10PQ | RT-R50A10PQ | RT-R60A10PQ | |
| RT-R40D07PQ | RT-R50D10PQ | RT-R60D10PQ | |
| RT-R40D10PQ | RT-R50G07PQ | RT-R60G07PQ | |
| RT-R40G07PQ | RT-R50G10PQ | RT-R60G10PQ | |
| RT-R40G10PQ | | | |