Rev. 01
DoC No. DOC-DC-0061837
Reference to. DC-0061837

# 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:

**Ryurei**

[CARDIAC ANGIOGRAPHY DEVICES]

**Intended purpose:** The Ryurei ("dilatation catheter") is intended to be used for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in the localized stenotic lesion of the coronary arteries.
The Ryurei (balloon models 2.0 mm to 4.0 mm) is also intended for post-deployment expansion of balloon-expandable stents.
Note: Bench testing was conducted with Ryurei ("dilatation catheter") and marketed Terumo balloon expandable stents.
Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design. All stents should be deployed in accordance with the manufacturer's indications for use.

**Basic UDI-DI:** 498735026DCRRLU

**Related product codes: See Appendix A (full list of active codes)**

declare that the above product of **Class III** 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 52.3 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 Chapter I & III (EU quality management system certificate number MDR 736706 R000), and Annex IX Chapter II (EU technical documentation assessment certificate number MDR 736802 R000), under the supervision of BSI Group The Netherlands B.V. as Notified Body authorized by the Netherlands Competent Authority and carrying the Notified Body No. 2797.

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

Authorised Representative: TERUMO EUROPE N.V.
Authorised Address: Interleuvenlaan 40, 3001 Leuven, Belgium
with Single Registration Number: BE-AR-000001433

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

Tokyo, 2023-08-04
(place and date of issue)

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ıager
Quality Assurance Department
For and on behalf of
TERUMO CORPORATION

## Appendix A – Related product codes

| Product code | UDI-DI |
|---|---|
| DC-RR1005HH | 04987892037153 |
| DC-RR1205HH | 04987892037177 |
| DC-RR1210HH | 04987892037191 |
| DC-RR1215HH | 04987892037214 |
| DC-RR1220HH | 04987892037238 |
| DC-RR1505HH | 04987892037276 |
| DC-RR1510HH | 04987892037290 |
| DC-RR1515HH | 04987892037313 |
| DC-RR1520HH | 04987892037337 |
| DC-RR2010HHW | 04987892037351 |
| DC-RR2015HHW | 04987892037375 |
| DC-RR2020HHW | 04987892037399 |
| DC-RR2030HHW | 04987892037412 |
| DC-RR2040HHW | 04987892037436 |
| DC-RR2210HHW | 04987892037450 |
| DC-RR2215HHW | 04987892037474 |
| DC-RR2220HHW | 04987892037498 |
| DC-RR2510HHW | 04987892037511 |
| DC-RR2515HHW | 04987892037535 |
| DC-RR2520HHW | 04987892037559 |
| DC-RR2530HHW | 04987892037573 |
| DC-RR2540HHW | 04987892037597 |

| Product code | UDI-DI |
|---|---|
| DC-RR2710HHW | 04987892037610 |
| DC-RR2715HHW | 04987892037634 |
| DC-RR2720HHW | 04987892037658 |
| DC-RR3010HHW | 04987892037672 |
| DC-RR3015HHW | 04987892037696 |
| DC-RR3020HHW | 04987892037719 |
| DC-RR3030HHW | 04987892037733 |
| DC-RR3040HHW | 04987892037757 |
| DC-RR3210HHW | 04987892037771 |
| DC-RR3215HHW | 04987892037795 |
| DC-RR3220HHW | 04987892037818 |
| DC-RR3510HHW | 04987892037832 |
| DC-RR3515HHW | 04987892037856 |
| DC-RR3520HHW | 04987892037870 |
| DC-RR3530HHW | 04987892037894 |
| DC-RR3540HHW | 04987892037917 |
| DC-RR3710HHW | 04987892037931 |
| DC-RR3715HHW | 04987892037955 |
| DC-RR3720HHW | 04987892037979 |
| DC-RR4010HHW | 04987892037993 |
| DC-RR4015HHW | 04987892038013 |
| DC-RR4020HHW | 04987892038037 |