

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)

A handwritten signature in blue ink, appearing to read "Toshio Nakashima".

Toshio Nakashima
General Manager
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