

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 736802 R000

Manufacturer: Terumo Corporation

Address:

44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

Single Registration Number: JP-MF-000017478

EU Authorised Representative: Terumo Europe N.V.

Address:

Interleuvenlaan 40
3001 Leuven
Belgium

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-10-19**

Current Issue Date: **2023-04-19**

Starting Validity Date: **2023-04-19**

Expiry Date: **2027-10-18**

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Device Schedule:

Device name: Ryurei

Intended Purpose as per the Instructions for Use:

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.

Type (Codes as per (EU) 2017/2185): MDN 1203

Risk Classification: Class III

Basic UDI-DI: 498735026DCRRLU

Model	Description (Balloon diameter, Balloon length)
DC-RR1005HH	1.00 mm, 5 mm
DC-RR1205HH	1.25 mm, 5 mm
DC-RR1210HH	1.25 mm, 10 mm
DC-RR1215HH	1.25 mm, 15 mm
DC-RR1220HH	1.25 mm, 20 mm
DC-RR1505HH	1.50 mm, 5 mm
DC-RR1510HH	1.50 mm, 10 mm
DC-RR1515HH	1.50 mm, 15 mm
DC-RR1520HH	1.50 mm, 20 mm
DC-RR2010HHW	2.00 mm, 10 mm
DC-RR2015HHW	2.00 mm, 15 mm
DC-RR2020HHW	2.00 mm, 20 mm
DC-RR2030HHW	2.00 mm, 30 mm
DC-RR2040HHW	2.00 mm, 40 mm
DC-RR2210HHW	2.25 mm, 10 mm
DC-RR2215HHW	2.25 mm, 15 mm
DC-RR2220HHW	2.25 mm, 20 mm

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Model	Description (Balloon diameter, Balloon length)
DC-RR2510HHW	2.50 mm, 10 mm
DC-RR2515HHW	2.50 mm, 15 mm
DC-RR2520HHW	2.50 mm, 20 mm
DC-RR2530HHW	2.50 mm, 30 mm
DC-RR2540HHW	2.50 mm, 40 mm
DC-RR2710HHW	2.75 mm, 10 mm
DC-RR2715HHW	2.75 mm, 15 mm
DC-RR2720HHW	2.75 mm, 20 mm
DC-RR3010HHW	3.00 mm, 10 mm
DC-RR3015HHW	3.00 mm, 15 mm
DC-RR3020HHW	3.00 mm, 20 mm
DC-RR3030HHW	3.00 mm, 30 mm
DC-RR3040HHW	3.00 mm, 40 mm
DC-RR3210HHW	3.25 mm, 10 mm
DC-RR3215HHW	3.25 mm, 15 mm
DC-RR3220HHW	3.25 mm, 20 mm
DC-RR3510HHW	3.50 mm, 10 mm
DC-RR3515HHW	3.50 mm, 15 mm
DC-RR3520HHW	3.50 mm, 20 mm
DC-RR3530HHW	3.50 mm, 30 mm
DC-RR3540HHW	3.50 mm, 40 mm
DC-RR3710HHW	3.75 mm, 10 mm
DC-RR3715HHW	3.75 mm, 15 mm
DC-RR3720HHW	3.75 mm, 20 mm
DC-RR4010HHW	4.00 mm, 10 mm
DC-RR4015HHW	4.00 mm, 15 mm
DC-RR4020HHW	4.00 mm, 20 mm

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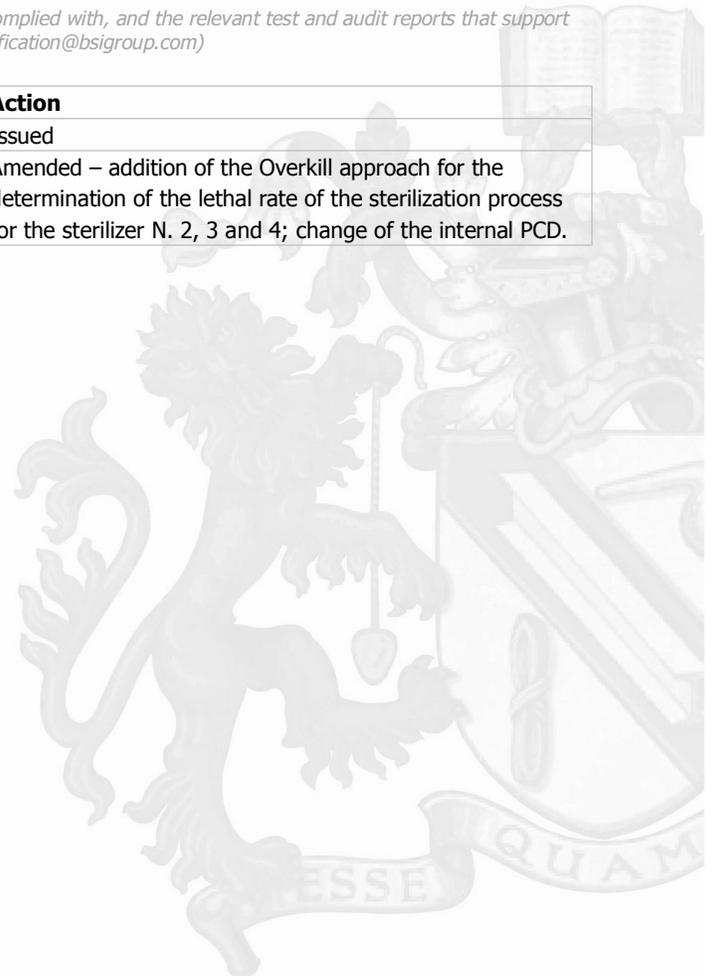
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-10-19	3294819	Issued
Current	3871615	Amended – addition of the Overkill approach for the determination of the lethal rate of the sterilization process for the sterilizer N. 2, 3 and 4; change of the internal PC.D.



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