By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 736706 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 examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graem

First Issue Date: **2021-11-11**

Current Issue Date: **2023-09-20**

Starting Validity Date: **2023-09-20**

Expiry Date: **2026-11-10**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Runthrough NS PTCA Guidewire	See MDR 736808
Ryujin Plus ("dilatation catheter")	See MDR 736794
Ryurei ("dilatation catheter")	See MDR 736802
FINECROSS MG ("coronary micro-guide catheter")	See MDR 736805
Progreat ("micro catheter system")	See MDR 736806
FineCross M3 ("coronary micro-guide catheter")	See MDR 774617

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Runthrough NS Extension Wire	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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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
2021-11-11	3294813	Issued.
2022-08-30	3718800	Amended – Addition of SRN for the Legal Manufacturer. Supplemented - Addition of Ryujin Plus to Device Schedule.
2022-10-19	3748470	Amended – Administrative update to Device Schedule (Ryujin Plus ("dilatation catheter")). Supplemented – Addition of Ryurei to Device Schedule.
2022-12-02	3776478	Supplemented – Addition of FINECROSS MG, Progreat, and Runthrough NS Extension Wire to Device Schedule. Amended – Removal of Subcontractor page from certificate.
Current	30007381	Supplemented – Addition of FineCross M3 to the Device Schedule.

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