By Royal Charter

EU Technical Documentation Assessment Certificate

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

MDR 736808 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 Global Regulatory & Quality

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

Current Issue Date: **2024-05-06**

Starting Validity Date: **2024-05-06**

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

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Device Schedule:

Intended Purpose as per the Instructions for Use:

The RUNTHROUGH NS is indicated to be used to guide interventional devices to a lesion for percutaneous transluminal coronary angioplasty (PTCA) for the purpose of improving myocardial blood flow in a stenotic lesion in coronary vessels. Do not use for any other purpose.

Risk Classification: Class III

Basic UDI-DI: 498735026TWNST6

Device Name	**Catalogue Number**	**Model**	**Type** (Codes as per (EU) 2017/2185)
Runthrough NS PTCA Guidewire	TW-AS418FA	Floppy	MDN 1203
	TW-DS418FH	Hypercoat	
	TW-AS418XA	Extra Floppy	
	TW-DS418IA	Intermediate	

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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	3294907	Issued
Current	30028520	Amended - addition of new manufacturing and sterilization subcontractor for Extra Floppy and Floppy model; EtO sterilization process change: addition of EtO sterilization validation approach (Overkill method) and change of IPCD supplier; addition of the SRN number in the certificate.

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