



## 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:

**Runthrough NS**

[CORONARY ARTERY THERAPEUTIC GUIDEWIRES]

### Intended purpose:

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.

**Basic UDI-DI: 498735026TWNST6**

### Related product codes:

Product code	UDI-DI	Manufacturing site
TW-AS418FA	04987350673855	Ashitaka factory
	04987350744548	Terumo Yamaguchi Corporation
TW-DS418FH	04987350105974	Ashitaka factory
TW-AS418XA	04987350427298	Ashitaka factory
	04987350744524	Terumo Yamaguchi Corporation
TW-DS418IA	04987350672711	Ashitaka factory

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 736808 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 , 2024-10-14

(place and date of issue)

署名者:

*hiroki sasagawa*



署名者名: hiroki sasagawa

署名理由: この文書を承認する

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Hiroki Sasagawa  
General Manager  
Quality Assurance Department  
For and on behalf of  
TERUMO CORPORATION