

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

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

being the manufacturer of:

Runthrough NS
PTCA Guide Wire

Product : Cardiac Catheter Guide Wire

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II excluding Section 4 (Certificate No.: CE 554734), and Annex II Section 4 (Certificate No.: CE 613749) under the supervision of BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, as Notified Body authorized by the Netherlands Competent Authority and carrying the Notified Body No. 2797.

Authorized European Representative:

TERUMO EUROPE N.V.

Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, July 30, 2019

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION



Appendix A - List of Code Number Structure

T W - □ □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11

Character number	Character & Meaning	
1-2	Product name	TW : TERUMO PTCA GUIDEWIRE
3	Destination	<u>—</u> : for domestic market/export
4	Shaft material	A : Ni-Ti + SUS302 ; D : Ni-Ti + SUS302 (for complex severely-stenosed lesions)
5	Tip configuration	S : Straight
6	Outer diameter	4 : 0.014"
7-8	Overall length (cm)	18 : 180 30 : 300
9	Tip flexibility, Support type	X : Extra Floppy·Normal Support F : Floppy·Normal Support I : Intermediate·Normal Support
10	Coil coating	H : Hydrophilic polymer (full coat) A : Hydrophilic polymer (silicone over 2 mm in distal)
11	Number of product contained	Z : 1 product Blank : 5 products



Appendix B - List of Product Code

Outer diameter (inch)	Product code	Specification			
		Length (cm)	Tip flexibility	Coil coating	Products per box (set/box)
0.014"	TW-AS418FA	180	Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-AS418FAZ	180	Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	1
	TW-AS418XA	180	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-AS418XAZ	180	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	1
	TW-AS430XA	300	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-AS430XAZ	300	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	1
	TW-DS418IA	180	Intermediate	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-DS418IAZ	180	Intermediate	Hydrophilic coating (Silicone coating over distal 2mm)	1
	TW-DS418FH	180	Floppy	Hydrophilic coating (Full)	5
	TW-DS418FHZ	180	Floppy	Hydrophilic coating (Full)	1