

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**

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

being the manufacturer of:

Navicross

Support Catheter

Product : Catheter, Intravascular, Guiding

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :

TERUMO EUROPE N.V.

Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A and B

Tokyo, February 10, 2020

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION



Appendix A - List of Code Number Structure

W S * N □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters	Meanings
1-2	Product	WS : Terumo Support catheter
3	Destination	* : for export
4	Classification	N : OTW (Over the Wire)
5	Tip shape	A : Angle30° S : Straight
6-7	Guidewire compatibility	35 : 0.035inch
8-9	Effective catheter length	0G : 65cm, 09 : 90cm, 0N : 135cm, 15 : 150cm
10	Number of Radiopaque markers	3
11	Hydrophilic coating on the distal portion	H : 400mm
12	Language for labeling	M : Multi-language M26



Appendix B - List of Code Number Structure

P N * N □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters	Meanings
1-2	Product	PN : Support Catheter for peripheral vasculature
3	Destination	* : for export
4	Classification	N : OTW (Over the Wire)
5	Tip shape	A : Angle30° S : Straight
6-7	Guidewire compatibility	18 : 0.018inch
8-9	Effective catheter length	0G : 65cm, 09 : 90cm, 0N : 135cm, 15 : 150cm
10	Number of Radiopaque markers	3
11	Hydrophilic coating on the distal portion	H : 400mm
12	Language for labeling	M : Multi-language M27