

## **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 60077473 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

Tokyo, July 4, 2013

(place and date of issue)

  
Hiroshi Nakagomi

General Manager

Quality Assurance Department

TERUMO CORPORATION

 **TERUMO®**

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