

DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

Heartrail II
Guiding Catheter

Product : Catheter, intravascular, guiding

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 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60108681 0001) under the supervision of TÜV Rheinland Product Safety GmbH, 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, February 10, 2020

(place and date of issue)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

Appendix A - List of Code Number Structure

G C - □ □ □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters	Meanings
1-2	Product	GC: Guiding catheter
3	Destination	- : for export and domestic
4	Trade Name	K: for coronary use P: for peripheral use F: for coronary use (for Asia and Australia)
5	Catheter size	5: 5Fr 6:6Fr 7:7Fr
6	Type of Catheter	A~Z 0~9
7	(shape type)	A~Z 0~9
8	Tip shape (length, radius, angle and other factors of curve to make shape)	A~Z 0~9
9		A~Z 0~9
10	Effective catheter length	R:85cm, 0:100cm, 2:120cm,
11	Side hole	Number of side holes : 0 1 2 3 Character : N 1 A K
12	Types of raw material	Q: 5Fr. ST, catheter length 120cm type NA: others