TERUMO

No.DOC-DQ010- 0797

Rev.10

DECLARATION OF CONFORMITY

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

being the manufacturer of:

Destination

Guiding Sheath

Product : Guiding Sheath

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 60134974 0001) under the supervision of TÜV Rheinland LGA Products 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

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 23:39:02 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A - List of Code Number Structure

Product code system_Destination

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

Character number	Denotation
1-2	Product **GS**: Guiding sheath
3	Destination: *: for export
4	Sheath type **F**: Floppy type, **K**: gradual transition type
5	Size **5**: 5Fr
6-8	Tip shape **ST1**: Straight (ST) **MP1**: Multi-purpose (MP) **HS1**: Hockey stick (HS) **RDC**: Renal double curve (RDC) **LIM**: Left internal mammary artery (LIMA)
9	Haemostatic mechanism **C**: Haemostasis valve (CCV) **T**: Y connector (TBV)
10-11	Effective length of the catheter Character **45** **90** Length (cm) 45 90
12	Length of hydrophilic coating Catheter NA*1 B Length(cm) 5 15

*1 : Not Applicable (any character is not indicated)