

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

Product code system_Destination

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 <div> Character 45 90 </div> <div> Length (cm) 45 90 </div>
12	Length of hydrophilic coating <div> Catheter NA^{*1} B </div> <div> Length(cm) 5 15 </div>

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