TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60134974 0001

Report No.: 12022672 002

Manufacturer:

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Product Identification:

Guiding Sheath

Type: Destination
Product code system: see attachment

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex II, section 4 of the directive 93/42/EEC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2023-12-08

Effective Date: 2018-12-09

Date: 2018-12-09

Notified Body

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:35:34 EEST
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Location: Moldova

TÜV Rheinland
LGA Products GmbH
Tillystraße 2 - 90431 Nürnberg

Attachment to Registration No.: ID 60134974 0001
Report No.: 12022672 002

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Scope: Guiding Sheath, Type Destination

Product code system

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)

Notified Body

Date : 2018-12-09

Dipl.-Ing. S. Pane