

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 - 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.

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 | * | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 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)

Date : 2018-12-09


 Notified Body

 Dipl.-Ing. S. Pane