

**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



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.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2 - 90431 Nürnberg**

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

**Manufacturer:** Terumo Corporation  
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Shibuya-Ku, Tokyo 151-0072  
Japan

**Scope:** Guiding Sheath, Type Destination

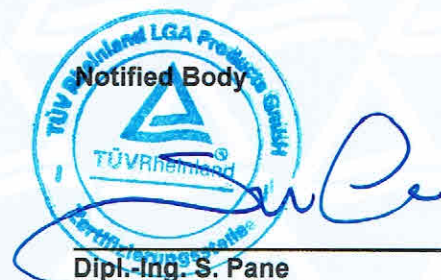
Product code system

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

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