

**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