

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
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Scope: Guiding Sheath, Type Destination

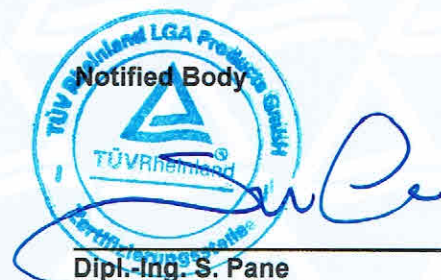
Product code system

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)

Date : 2018-12-09



Notified Body
TÜVRheinland
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