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: 2020.09.09 15:35:04 EEST
Reason: MoldSign Signature
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

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145252 0001

Report No.: 12031336 018

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

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-23

Date: 2019-12-23

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

M.aihara

M.Sc. M. Aihara

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 15:35:36 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-12-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-12-23

M.Aihara

M.Sc. M. Aihara

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

Scope:
Design and Development, Manufacture, Distribution and Service of
- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Endoscopic Vessel Harvesting System
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TERUMO

No.DOC-DQ010- 0797

Rev.10

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

Destination

Guiding Sheath

Product : Guiding Sheath

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60134974 0001) under the supervision of TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, February 10, 2020
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:35:32 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A - List of Code Number Structure

Product code system_Destination

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)

Destination®

Peripheral Guiding Sheath

Destination® Guiding Sheath is designed to perform as a guiding catheter and an introducer sheath.

Destination® is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to lower extremity, renal arteries, and carotid arteries.

Product Characteristics

- *Coil reinforcement inside the sheath which provides high anti-kinking characteristics*
- *Hydrophilic coating at the distal part of the sheath for good trackability*
- *Secured hemostasis tailored by Terumo's unique cross-cut valve (CCV items)*
- *Soft atraumatic tip*
- *PTFE inner layer which provides smooth device passage*
- *5 different tip configurations available*

General Specifications

Maximum guidewire size	0.038" / 0.97 mm
Radiopaque marker	Gold coil marker at 5 mm from the distal tip of the sheath
Reinforcement inside the sheath	Stainless steel coil
Sheath inner layer	PTFE polytetrafluoroethylene

Item Specifications

Inner diameter	Length	Shape	Valve	Hydrophilic coating length	Item reference
5 Fr / 0.076" / 1.9 mm	45 cm	Straight	CCV*	5 cm	GS*F5ST1C45
5 Fr / 0.076" / 1.9 mm	45 cm	Hockey stick	CCV	5 cm	GS*F5HS1C45
5 Fr / 0.076" / 1.9 mm	45 cm	Multipurpose	CCV	5 cm	GS*F5MP1C45
5 Fr / 0.076" / 1.9 mm	45 cm	Renal Double Curve	CCV	5 cm	GS*F5RDCC45
5 Fr / 0.076" / 1.9 mm	45 cm	Left Internal Mammary Artery	CCV	5 cm	GS*F5LIMC45
6 Fr / 0.087" / 2.2 mm	45 cm	Straight	CCV	5 cm	RSR01
6 Fr / 0.087" / 2.2 mm	45 cm	Hockey stick	CCV	5 cm	RSR02
6 Fr / 0.087" / 2.2 mm	45 cm	Multipurpose	CCV	5 cm	RSR03
6 Fr / 0.087" / 2.2 mm	45 cm	Renal Double Curve	CCV	5 cm	RSR13
6 Fr / 0.087" / 2.2 mm	45 cm	Left Internal Mammary Artery	CCV	5 cm	RSR14
7 Fr / 0.101" / 2.5 mm	45 cm	Straight	CCV	5 cm	RSR04
7 Fr / 0.101" / 2.5 mm	45 cm	Hockey stick	CCV	5 cm	RSR05
7 Fr / 0.101" / 2.5 mm	45 cm	Multipurpose	CCV	5 cm	RSR06
7 Fr / 0.101" / 2.5 mm	45 cm	Renal Double Curve	CCV	5 cm	RSR15
7 Fr / 0.101" / 2.5 mm	45 cm	Left Internal Mammary Artery	CCV	5 cm	RSR16
8 Fr / 0.115" / 2.9 mm	45 cm	Straight	CCV	35 cm	54-84501
6 Fr / 0.087" / 2.2 mm	65 cm	Straight	CCV	35 cm	RSP01
7 Fr / 0.101" / 2.5 mm	65 cm	Straight	CCV	35 cm	RSP02
8 Fr / 0.115" / 2.9 mm	65 cm	Straight	CCV	35 cm	54-86501
5 Fr / 0.076" / 1.9 mm	90 cm	Straight	TBV**	15 cm	GS*K5ST1T90B
5 Fr / 0.076" / 1.9 mm	90 cm	Multipurpose	TBV	15 cm	GS*K5MP1T90B
5 Fr / 0.076" / 1.9 mm	90 cm	Straight	CCV	15 cm	GS*K5ST1C90B
5 Fr / 0.076" / 1.9 mm	90 cm	Multipurpose	CCV	15 cm	GS*K5MP1C90B

*CCV = cross-cut valve. **TBV = Tuohy-Borst Valve.

Inner diameter	Length	Shape	Valve	Hydrophilic coating length	Item reference
6 Fr / 0.087" / 2.2 mm	90 cm	Straight	TBV	15 cm	RSC01
6 Fr / 0.087" / 2.2 mm	90 cm	Multipurpose	TBV	15 cm	RSC03
6 Fr / 0.087" / 2.2 mm	90 cm	Straight	CCV	15 cm	RSC05
6 Fr / 0.087" / 2.2 mm	90 cm	Multipurpose	CCV	15 cm	RSC07
7 Fr / 0.101" / 2.5 mm	90 cm	Straight	TBV	15 cm	RSC02
7 Fr / 0.101" / 2.5 mm	90 cm	Multipurpose	TBV	15 cm	RSC04
7 Fr / 0.101" / 2.5 mm	90 cm	Straight	CCV	15 cm	RSC06
7 Fr / 0.101" / 2.5 mm	90 cm	Multipurpose	CCV	15 cm	RSC08
8 Fr / 0.115" / 2.9 mm	90 cm	Straight	CCV	60 cm	54-89001
8 Fr / 0.115" / 2.9 mm	90 cm	Straight	TBV	60 cm	54-89006

All dilators are 0.038" (0.97 mm) wire compatible
Please quote above item reference codes when placing an order

IS616/42GB0616IT1

Not secure | 89.32.230.138:8081/dispozitive/

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conformitate CE
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		Destination				Terumo				
DM000186931	TEACĂ DE GHIDARE PENTRU CATETER INTRAVASCULAR	DESTINATION®	GUIDING SHEATH		Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-343	26-11-2018	

Содержит([NameMake], 'Destination') И Содержит([Producatorul], 'Terumo')

Очист