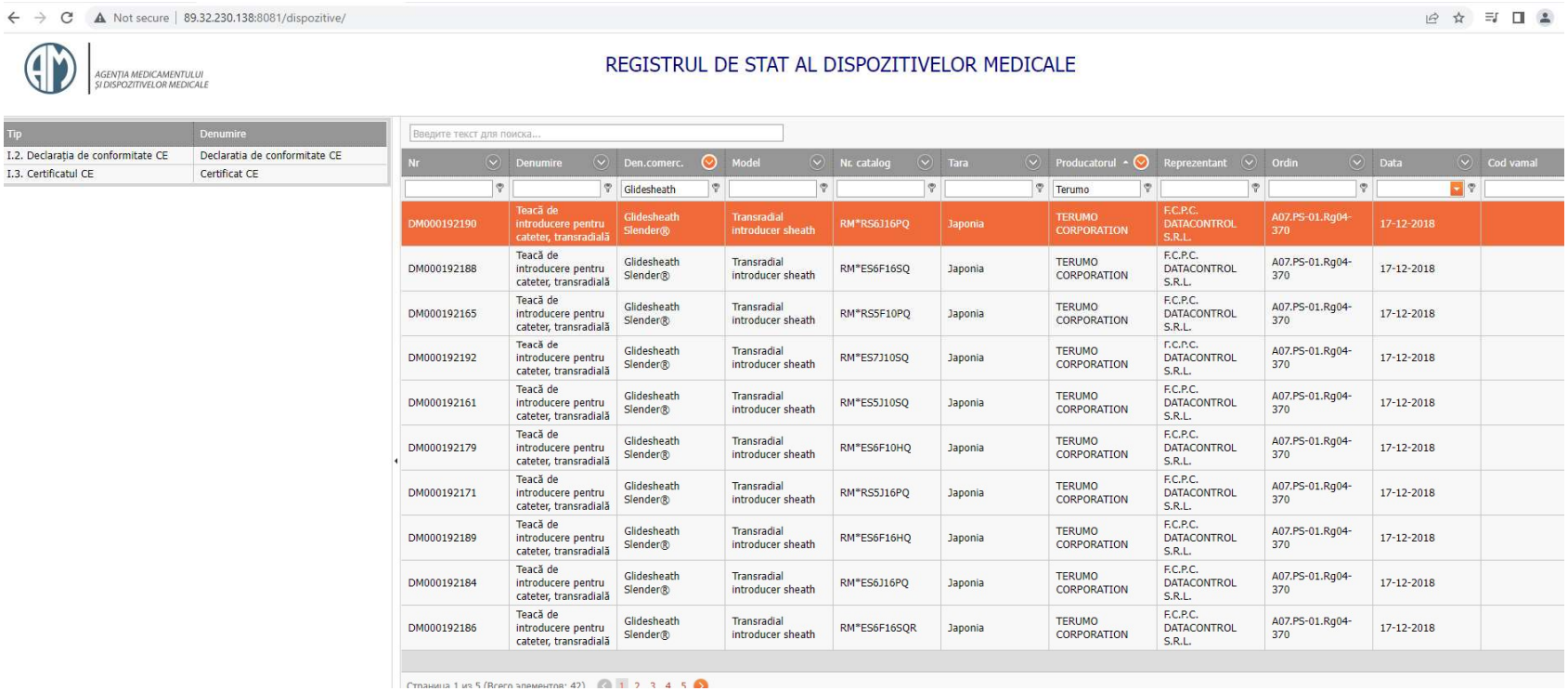

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AGENTIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

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
		Glidesheath				Terumo				
DM000192190	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*RS6J16PQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192188	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*ES6F16SQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192165	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*RS5F10PQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192192	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*ES7J10SQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192161	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*ES5J10SQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192179	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*ES6F10HQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192171	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*RS5J16PQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192189	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*ES6F16HQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192184	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*ES6J16PQ	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	
DM000192186	Teacă de introducere pentru cateter, transradială	Glidesheath Slender®	Transradial introducer sheath	RM*ES6F16SQR	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-370	17-12-2018	

Страница 1 из 5 (Всего элементов: 42) 1 2 3 4 5

Digitally signed by Grabazei Alexandru
Date: 2023.02.02 16:30:13 EET
Reason: MoldSign Signature
Location: Moldova

Glidesheath Slender®

Transradial Introducer Sheath

Glidesheath Slender offers the smallest option for procedures requiring 5, 6, and 7 Fr sheaths[1].
The proprietary thin-wall technology reduces the outside diameter of the introducer sheath by 1Fr while maintaining a larger inner-diameter equivalent.

Product Characteristics

- *Thin wall leading to a 1Fr reduction in outer diameter.*
- *A smaller diameter sheath reduces the arteriotomy size, to enhance post-procedure hemostasis[2].*
- *Easy insertion and removal with proprietary Terumo M Coat™ hydrophilic coating.*
- *Designed towards minimise mechanical irritation to the artery.*
- *Less penetration resistance than conventional sheaths.[2, 3]*

1 Saito S et al. Catheter Cardiovasc Interv 1999;46:173-178
2 Rao S et al. Eur Heart J 2012;33:2521-2526
3 Saito S et al. Catheter Cardiovasc Interv 2002;56:328-332

IS803/15GB1219KAIII

Item specifications

Outer Diameter	Sheath Length	Entry Needle - Diameter	Entry Needle - Length	Entry Needle - Type	Mini Guidewire - Type	Mini Guidewire - Diameter	Mini Guidewire - Length	Code
5 Fr	10 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	45 cm	RM*RS5J10PQ
5 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	45 cm	RM*ES5J10SQ
5 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	45 cm	RM*ES5J10PQ
5 Fr	10 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	45 cm	RM*RS5F10PQ
5 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES5F10SQR
5 Fr	10 cm	22 G 0.7 mm	35 mm	Metallic Entry Needle	Spring	0.018 in 0.46 mm	45 cm	RM*RS5C10PQ
5 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES5J16HQS
5 Fr	16 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	80 cm	RM*RS5J16PQ
5 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	80 cm	RM*ES5J16SQ
5 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	80 cm	RM*ES5J16PQ
5 Fr	16 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	80 cm	RM*RS5F16PQ
5 Fr	16 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES5F16SQR
6 Fr	10 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	45 cm	RM*ES6J10HQS
6 Fr	10 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	45 cm	RM*RS6J10PQ
6 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	45 cm	RM*ES6J10SQ
6 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	45 cm	RM*ES6J10PQ
6 Fr	10 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	45 cm	RM*RS6F10PQ
6 Fr	10 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES6F10SQ
6 Fr	10 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	45 cm	RM*ES6F10HQR
6 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES6F10SQR
6 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	45 cm	RM*ES6F10HQ
6 Fr	10 cm	22 G 0.7 mm	35 mm	Metallic Entry Needle	Spring	0.018 in 0.46 mm	45 cm	RM*RS6C10PQ
6 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	80 cm	RM*ES6J16HQS
6 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	80 cm	RM*ES6J16PQ
6 Fr	16 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	80 cm	RM*RS6J16PQ
6 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	80 cm	RM*ES6J16SQ
6 Fr	16 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	80 cm	RM*RS6F16PQ
6 Fr	16 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	80 cm	RM*ES6F16SQ
6 Fr	16 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES6F16HQ
6 Fr	16 cm	22 G 0.7 mm	25 mm	Plastic IV Catheter	Plastic Shortangle	0.021 in 0.53 mm	80 cm	RM*ES6F16HQR
6 Fr	16 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	80 cm	RM*ES6F16SQR
7 Fr	10 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	45 cm	RM*ES7J10HQS
7 Fr	10 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	45 cm	RM*RS7J10PQ
7 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	45 cm	RM*ES7J10SQ
7 Fr	10 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	45 cm	RM*ES7J10PQ

Please quote above item reference codes when placing an order

IS803/15GB1219IKAIII

Item specifications

Outer Diameter	Sheath Length	Entry Needle - Diameter	Entry Needle - Length	Entry Needle - Type	Mini Guidewire - Type	Mini Guidewire - Diameter	Mini Guidewire - Length	Code
7 Fr	10 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	45 cm	RM*RS7F10PQ
7 Fr	10 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	45 cm	RM*ES7F10SQR
7 Fr	16 cm	20 G 0.9 mm	32 mm	Plastic IV Catheter	Plastic Shortangle	0.025 in 0.64 mm	80 cm	RM*ES7J16HQS
7 Fr	16 cm	20 G 0.9 mm	35 mm	Metallic Entry Needle	Spring	0.025 in 0.64 mm	80 cm	RM*RS7J16PQ
7 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Plastic	0.025 in 0.64 mm	80 cm	RM*ES7J16SQ
7 Fr	16 cm	20 G 0.9 mm	51 mm	Plastic IV Catheter	Spring	0.025 in 0.64 mm	80 cm	RM*ES7J16PQ
7 Fr	16 cm	21 G 0.8 mm	35 mm	Metallic Entry Needle	Spring	0.021 in 0.53 mm	80 cm	RM*RS7F16PQ
7 Fr	16 cm	22 G 0.7 mm	32 mm	Plastic IV Catheter	Plastic	0.021 in 0.53 mm	80 cm	RM*ES7F16SQR

Please quote above item reference codes when placing an order

IS803/15GB1219KAIII

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III

Notified Body

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 15:34:36 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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Installation and serving of active medical devices.

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.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
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 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TERUMO EUROPE N.V. Interleuvenlaan 40 3001 Leuven Belgium	Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories. Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices. Installation and serving of active medical devices
/02	c/o Terumo Europe UK 3 Unity Grove Knowsley Business Park South Merseyside, Knowsley L34 9GT United Kingdom	Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
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 1594584-1

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/03	c/o Terumo Deutschland GmbH Ludwig-Erhard-Str. 6 65760 Eschborn Germany	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/04	c/o Terumo France S.A.S. Bâtiment Renaissance, 3 rond-point des Saules 78280 Guyancourt France	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/05	c/o Terumo Italia S.r.l. Via Paolo di Dono 73 00142 Roma Italy	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/06	c/o Terumo Europe España SL Avda. Juan Carlos I, N°13-7 Planta 28806 Alcalá de Henares (Madrid) Spain	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
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 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/07	c/o Terumo Europe UK Ltd. Otium House 2 Freemantle Road Bagshot Surrey GU19 5LL United Kingdom	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/08	c/o Terumo Europe N.V. Benelux Sales Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/09	c/o Terumo Sweden AB Sven Källfets gata 16 SE-426 71 Västra Frölunda Sweden	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/10	c/o Terumo Deutschland GmbH Zweigniederlassung Switzerland Bodenäckerstrasse 3 8957 Spreitenbach Switzerland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
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 1594584-1

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/11	c/o Terumo Europe N.V. European Distribution Center Brikkenovenstraat 48 3600 Genk Belgium	Storage and distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/12	c/o Terumo Europe N.V. Terumo Interventional Systems EMEA (TIS-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/13	c/o Terumo Europe N.V. Terumo Cardiovascular Europe Middle East & Africa (TCV-EMEA) Ludwig-Erhard-Straße 6 65760 Eschborn Germany	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

D. Wiedemuth

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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 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/14	c/o Terumo Europe N.V. Terumo Medical Products EMEA (TMP-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/15	c/o Terumo Europe N.V. Diabetes Management EMEA (DM-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/16	c/o Terumo Europe N.V. Terumo Pharmaceutical Solutions Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices and active implantable medical devices
/17	c/o Terumo Deutschland GmbH Zweigniederlassung Austria Liebermannstrasse F10-301 2345 Brunn am Gebirge Austria	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/18	c/o Terumo Europe N.V. Emerging Market Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/19	c/o Terumo Poland Sp. Zoo Wisniowy Business Park budynek D ul. 1 Sierpnia 6 02-134 Warszawa Poland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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

EC Certificate

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

Registration No.: HD 60134707 0001

Report No.: 21240046 017

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products: (see attachment for products and additional sites included)

Replaces Certificate, Registration No.: HD 60106290 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.

Notified Body

Effective Date: 2020-04-21

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products included:

- Syringes
- Needles
- Administration sets
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Introducer for vascular access
- Angiographic Catheters
- Guidewire for Angiography

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

additional sites included:

Terumo Europe N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Terumo Europe UK
3 Unity Grove, Knowsley Business Park South
Knowsley, Merseyside L34 9GT, United Kingdom

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüf- und Zertifizierungsstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth