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AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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

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Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		INTRODUCER					data			
DM000137002	SET INTRODUCTOR PENTRU CATETER	RADIFOCUS® INTRODUCER II			SUA	TERUMO MEDICAL CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-188	16-07-2018	
DM000137003	SET INTRODUCTOR PENTRU CATETER	RADIFOCUS® INTRODUCER II	WITH R/O MARKER		SUA	TERUMO MEDICAL CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-188	16-07-2018	
DM000117583	SET INTRODUCATOR PENTRU CATETERE	RADIFOCUS® INTRODUCER II			Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-124	14-05-2018	

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AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE
REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE
Tip
Denumire
I.2. Declarația de conformitate CE
Declaratie de conformitate CE
I.3. Certificatul CE
Certificat CE
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SET INTRODUCTOR PENTRU CATETER
FAST-CATH™ HEMOSTASIS INTRODUCER
6F
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ABBOTT MEDICAL
SANTE DISTRIBUȚIE S.R.L.
Rg04-000147
29-06-2021
DM000309296
SET INTRODUCTOR PENTRU CATETER
FAST-CATH™ HEMOSTASIS INTRODUCER
9F
406366
SUA
ABBOTT MEDICAL
SANTE DISTRIBUȚIE S.R.L.
Rg04-000147
29-06-2021
DM000309295
SET INTRODUCTOR PENTRU CATETER
FAST-CATH™ HEMOSTASIS INTRODUCER
8F
406362
SUA
ABBOTT MEDICAL
SANTE DISTRIBUȚIE S.R.L.
Rg04-000147
29-06-2021
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SET INTRODUCTOR PENTRU CATETER
FAST-CATH™ HEMOSTASIS INTRODUCER
7F
406358
SUA
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SANTE DISTRIBUȚIE S.R.L.
Rg04-000147
29-06-2021
DM000309292
SET INTRODUCTOR PENTRU CATETER
FAST-CATH™ HEMOSTASIS INTRODUCER
5F
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SANTE DISTRIBUȚIE S.R.L.
Rg04-000147
29-06-2021
DM000137002
SET INTRODUCTOR PENTRU CATETER
RADIFOCUS® INTRODUCER II
SUA
TERUMO MEDICAL CORPORATION
F.C.P.C. DATACONTROL S.R.L.
A07.PS-01.Rg04-188
16-07-2018
DM000137003
SET INTRODUCTOR PENTRU CATETER
RADIFOCUS® INTRODUCER II
WITH R/O MARKER
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TERUMO MEDICAL CORPORATION
F.C.P.C. DATACONTROL S.R.L.
A07.PS-01.Rg04-188
16-07-2018
DM000117583
SET INTRODUCATOR PENTRU CATETERE
RADIFOCUS® INTRODUCER II
Belgia
TERUMO EUROPE N.V.
F.C.P.C. DATACONTROL S.R.L.
A07.PS-01.Rg04-124
14-05-2018
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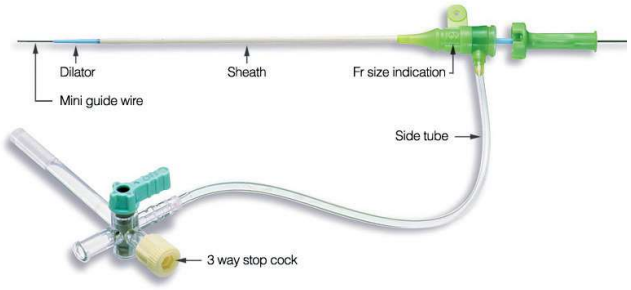
RADIFOCUS® Introducer II
STANDARD KIT

Introducer Sheath

Introducers are intended to be inserted percutaneously into a vessel to facilitate the entire interventional procedure.

Product Characteristics

- *Total Integrated Fit (TIF) tip tapering: optimal tapering design at the tip of the sheath and dilator for smooth penetration*
- *Cross-cut hemostasis valve: effectively protects against blood reflux and air aspiration*
- *Thin radiopaque sheath with anti-kinking sleeve: for excellent catheter handling*
- *Snap-on / click-off dilator lock: prevents dilator back-out during insertion and allows one-hand unlocking*
- *Wide variety of kit variations providing all elements for quick vessel access: 4 - 11 Fr sheaths, 5 - 25 cm lengths, Surflash or micro puncture metal needle*



Available Kits

- **A Kit** contains sheath, dilator, plastic mini guidewire and plastic IV catheter (entry needle)
- **B Kit** contains sheath, dilator, plastic or spring mini guidewire
- **C Kit** contains sheath and dilator
- **R Kit** contains sheath, dilator, spring mini guidewire and metallic entry needle

A Kit

General Specifications

Sheath length	10 cm
Mini guidewire	Plastic Straight and Angled 0.025" (0.64 mm) for 4 Fr, 0.035" (0.89 mm) for all others 45 cm
Entry needle	Plastic IV Catheter - 18G x 2 ½" (1.2 x 64 mm), except for 4 Fr : 20G x 2" (0.9 x 51 mm), 2.5 ml syringe is included
Guidewire compatibility	0.025" (0.64 mm) for 4 Fr 0.035" (0.89 mm) for all others
Packaging	Tray

Item Specifications

Inner diameter	Mini guidewire type	
	45 cm angled	45 cm straight
4 Fr	RS+A40K10AQ	RS+A40G10SQ
5 Fr	RS+A50K10AQ	RS+A50K10SQ
6 Fr	RS+A60K10AQ	RS+A60K10SQ
7 Fr	—	RS+A70K10SQ
8 Fr	—	RS+A80K10SQ
9 Fr	—	RS*A90K10SQ
10 Fr	—	RS*A10K10SQ
11 Fr	—	RS*A11K10SQ

Please quote above item reference codes when placing an order

B Kit

1st Type in tray with plastic mini guidewire

General Specifications

Sheath length	10 cm and 25 cm
Mini guidewire	Plastic Straight and Angled 0.025" (0.64 mm) or 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others 45 cm for 10 cm sheath and 80 cm for 25 cm sheath
Guidewire compatibility	0.025" (0.64 mm) or 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others
Packaging	Tray

Item Specifications

Inner diameter	Guidewire compatibility	Sheath length 10 cm		Sheath length 25 cm
		Mini guidewire type		
		45 cm angled	45 cm straight	80 cm angled
4 Fr	0.025" (0.64 mm)	—	RS+B40G10SQ	—
4 Fr	0.035" (0.89 mm)	RS+B40K10AQ	RS+B40K10SQ	—
5 Fr	0.038" (0.97 mm)	RS+B50N10AQ	RS+B50N10SQ	RS+B50N25AQ
6 Fr	0.038" (0.97 mm)	—	RS+B60N10SQ	RS+B60N25AQ
7 Fr	0.038" (0.97 mm)	—	RS+B70N10SQ	RS+B70N25AQ
8 Fr	0.038" (0.97 mm)	—	RS+B80N10SQ	RS+B80N25AQ
9 Fr	0.038" (0.97 mm)	—	RS*B90N10SQ	RS*B90N25AQ
10 Fr	0.038" (0.97 mm)	—	RS*B10N10SQ	RS*B10N25AQ
11 Fr	0.038" (0.97 mm)	—	RS*B11N10SQ	RS*B11N25AQ

Please quote above item reference codes when placing an order

B Kit

2nd Type in tray with spring mini guidewire

General Specifications

Sheath length	10 cm
Mini guidewire	Spring, J-type 0.035" (0.89 mm) and 0.038" (0.97 mm) 45 cm
Guidewire compatibility	0.035" (0.89 mm) or 0.038" (0.97 mm)
Packaging	Tray

Item Specifications

Inner diameter	Guidewire compatibility	
	0.035" (0.89 mm)	**0.038" (0.97 mm)**
4 Fr	RS+B40K10MQ	—
5 Fr	RS+B50K10MQ	RS+B50N10MQ
6 Fr	RS+B60K10MQ	RS+B60N10MQ
7 Fr	RS+B70K10MQ	RS+B70N10MQ
8 Fr	RS+B80K10MQ	RS+B80N10MQ
9 Fr	RS*B90K10MQ	RS*B90N10MQ
10 Fr	RS*B10K10MQ	RS*B10N10MQ
11 Fr	RS*B11K10MQ	RS*B11N10MQ

Please quote above item reference codes when placing an order

3rd Type in pouch with spring mini guidewire

General Specifications

Sheath length	10 cm
Mini guidewire	Spring J Angled 0.035" (0.89 mm) for all items
Guidewire compatibility	0.035" (0.89 mm) for 4Fr items 0.038" (0.97 mm) for all other items
Packaging	Pouch

Item Specifications

Inner diameter	Item reference
4 Fr	RS*B40K10MR
5 Fr	RS*B50N10MRD
6 Fr	RS*B60N10MRD
7 Fr	RS*B70N10MRD
8 Fr	RS*B80N10MRD
9 Fr	RS*B90N10MRD
10 Fr	RS*B10N10MRD
11 Fr	RS*B11N10MRD

Please quote above item reference codes when placing an order

C Kit

General Specifications

Sheath length	10 cm and 25 cm
Guidewire compatibility	0.025" (0.64 mm), 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others
Packaging	Pouch

Item Specifications

Inner diameter	Guidewire compatibility	Sheath length	
		10 cm	**25 cm**
4 Fr	0.025" (0.64 mm)	RS+C40G10NR	—
4 Fr	0.035" (0.89 mm)	RS+C40K10NR	RS+C40K25NR
5 Fr	0.038" (0.97 mm)	RS+C50N10NR	—
6 Fr	0.038" (0.97 mm)	RS+C60N10NR	RS+C60N25NR
7 Fr	0.038" (0.97 mm)	RS+C70N10NR	RS+C70N25NR
8 Fr	0.038" (0.97 mm)	RS+C80N10NR	RS+C80N25NR
9 Fr	0.038" (0.97 mm)	RS*C90N10NR	—
10 Fr	0.038" (0.97 mm)	RS*C10N10NR	—
11 Fr	0.038" (0.97 mm)	RS*C11N10NR	—

Please quote above item reference codes when placing an order

R Kit

General Specifications

Sheath length	10 cm
Mini guidewire	Spring, J-type 0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others 45 cm
Entry needle	Metallic entry needle - 18G x 2 ¾" (1.2 x 70 mm)
Guidewire compatibility	0.035" (0.89 mm) for 4 Fr and 0.038" (0.97 mm) for all others
Packaging	Tray

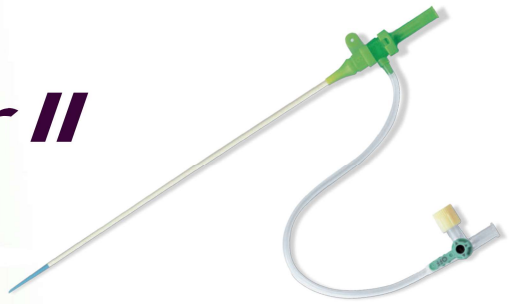
Item Specifications

Inner diameter	Item reference
4 Fr	RS+R40K10MQ
5 Fr	RS+R50N10MQ
6 Fr	RS+R60N10MQ
7 Fr	RS+R70N10MQ
8 Fr	RS+R80N10MQ
9 Fr	RS+R90N10MQ

Please quote above item reference codes when placing an order

IS616/3GB0616ITI

RADIFOCUS® Introducer II
TRANSRADIAL KIT



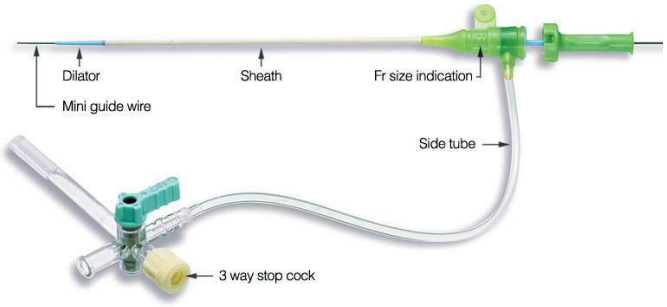
Introducer Sheath

Introducers are intended to be inserted percutaneously into a vessel to facilitate the entire interventional procedure.

Being a pioneer and a leader in vascular access, Terumo's goal is to offer complete solutions for transradial interventions with devices that minimize patient stress and optimize outcomes.

Product Characteristics

- *Total Integrated Fit (TIF) tip tapering: optimal tapering design at the tip of the sheath and dilator for smooth penetration*
- *Cross-cut hemostasis valve: effectively protects against blood reflux and air aspiration*
- *Thin radiopaque sheath with anti-kinking sleeve: for excellent catheter handling*
- *Snap-on / click-off dilator lock: prevents dilator back-out during insertion and allows one-hand unlocking*



Solution Nr. 1

Radifocus® Introducer II special transradial tapered Introducer Kit

- *Dilator internal tip diameter equals to mini guidewire external diameter*
- *Micro puncture metallic entry needle with short bevel (22G/21G/20G) equals to mini guidewire to minimize puncture site complications*

Available kits

R Kit contains sheath, dilator, spring mini guidewire and metallic entry needle.

General Specifications

Sheath length	7 cm and 10 cm
Mini guidewire	Spring Straight 0.018" (0.46 mm), 0.021" (0.53 mm) and 0.025" (0.64 mm) 45 cm
Entry needle	Metallic entry needle - 22G x 1 3/8 (0.7 x 35mm), 21G x 1 3/8 (0.8 x 35mm), 20G x 1 3/8 (0.9 x 35mm)
Guidewire compatibility	0.018" (0.46 mm), 0.021" (0.53 mm) and 0.025" (0.64 mm)
Packaging	Tray

Item Specifications

Inner diameter	Sheath length 7 cm			Sheath length 10 cm		
	Compatible with guidewire					
	0.018" (0.46 mm)	0.021" (0.53mm)	0.025" (0.64 mm)	0.018" (0.46 mm)	0.021" (0.53 mm)	0.025" (0.64 mm)
4 Fr	RT-R40A07PQ	RT-R40D07PQ*	RT-R40G07PQ	RT-R40A10PQ	RT-R40D10PQ	RT-R40G10PQ
5 Fr	RT-R50A07PQ	—	RT-R50G07PQ	RT-R50A10PQ	RT-R50D10PQ	RT-R50G10PQ
6 Fr	RT-R60A07PQ	—	RT-R60G07PQ	RT-R60A10PQ	RT-R60D10PQ	RT-R60G10PQ
7 Fr	—	—	—	—	RT-R70D10PQ	—

* This product may have additional lead time. Please contact your Terumo local representative.

Solution Nr. 2

Radifocus® Introducer II M Coat™, Introducer Kit with hydrophilic M Coating

- ***Dilator internal tip diameter equals to mini guidewire external diameter***
- ***Retrieving the M Coat™ sheath requires only half the force compared to conventional uncoated sheaths***

Available Kits

- **M Coat™ A Kit** contains sheath, dilator, plastic mini guidewire and plastic IV catheter (entry needle), 2.5 cc syringe
- **M Coat™ R Kit** contains sheath, dilator, spring mini guidewire and metallic entry needle

M Coat™ A Kit

General Specifications

Sheath length	10 cm, 16 cm and 25 cm
Sheath coating	Hydrophilic M Coat™
Mini guidewire	Plastic Straight 0.025" (0.64 mm) 45 cm for 10 cm sheath and 80 cm for 16 cm and 25 cm sheath
Entry needle	Plastic IV Catheter - 20G x 1 ¼" (0.9 x 32 mm) , 2.5 ml syringe is included
Guidewire compatibility	0.025" (0.64 mm)
Packaging	Tray

Item Specifications

Inner diameter	Sheath length		
	10 cm	**16 cm**	**25 cm**
5 Fr	RM*AF5J10SQW	RM*AF5J16SQW	RM*AF5J25SQW
6 Fr	RM*AF6J10SQW	RM*AF6J16SQW	RM*AF6J25SQW

Please quote above item reference codes when placing an order

M Coat™ R Kit

General Specifications

Sheath length	10 cm, 16 cm and 25 cm
Sheath coating	Hydrophilic M Coat™
Mini guidewire	Spring Straight 0.021" (0.53 mm) and 0.025" (0.64 mm) 45 cm for 10 cm sheath, 80 cm for 16 cm and 25 cm sheath
Entry needle	Metallic entry needle 21G x 1 2/5 (0.8 x 36 mm) 20G x 1 2/5 (0.9 x 36 mm)
Guidewire compatibility	0.021" (0.53 mm) and 0.025" (0.64 mm)
Packaging	Tray

Item Specifications

Inner diameter	Guidewire compatibility	Sheath length		
		10 cm	**16 cm**	**25 cm**
5 Fr	0.021" (0.53 mm)	RM*RF5F10PQ	RM*RF5F16PQ	RM*RF5F25PQ
5 Fr	0.025" (0.64 mm)	RM*RF5J10PQ	RM*RF5J16PQ	RM*RF5J25PQ
6 Fr	0.021" (0.53 mm)	RM*RF6F10PQ	RM*RF6F16PQ	RM*RF6F25PQ
6 Fr	0.025" (0.64 mm)	RM*RF6J10PQ	RM*RF6J16PQ	RM*RF6J25PQ

Please quote above item reference codes when placing an order

IS616/4GB0616ITI

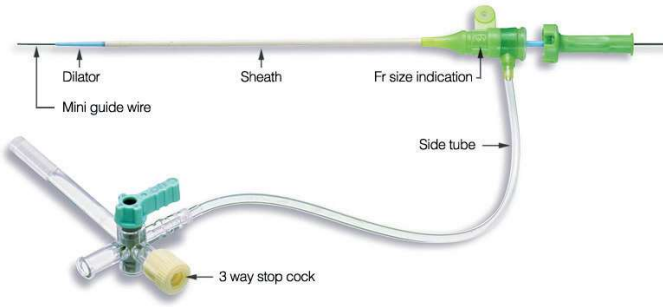
RADIFOCUS® Introducer II
PEDIATRIC KIT

Introducer Sheath

Introducers are intended to be inserted percutaneously into a vessel to facilitate the entire interventional procedure.

Product Characteristics

- *Total Integrated Fit (TIF) tip tapering: optimal tapering design at the tip of the sheath and dilator for smooth penetration*
- *Cross-cut hemostasis valve: effectively protects against blood reflux and air aspiration*
- *Thin radiopaque sheath with anti-kinking sleeve: for excellent catheter handling*
- *Snap-on / click-off dilator lock: prevents dilator back-out during insertion and allows one-hand unlocking*
- *Nitinol super elastic mini guidewire enables smooth insertion and removal*



Available Kits

- **A Kit** contains sheath, dilator, plastic mini guidewire and plastic IV catheter (entry needle), 2.5 cc syringe
- **B Kit** contains sheath, dilator and plastic mini guidewire

A Kit

General Specifications

Sheath length	5 cm and 7 cm
Mini guidewire	Plastic Straight 0.025" (0.64 mm) 45 cm
Guidewire compatibility	0.025" (0.64 mm)
Entry needle	Plastic IV catheter - 20G x 2" (0.9 x 51 mm), 2.5 ml syringe is included
Packaging	Tray

Item Specifications

Inner diameter	Sheath length	
	5 cm	**7 cm**
4 Fr	—	RS+A40G07SQ
5 Fr	RS*A50G05SQ	RS+A50G07SQ
6 Fr	RS*A60G05SQ	RS+A60G07SQ

Please quote above item reference codes when placing an order

B Kit

General Specifications

Sheath length	7 cm
Mini guidewire	Plastic Straight 0.025" (0.64 mm) 45 cm
Guidewire compatibility	0.025" (0.64 mm)
Packaging	Tray

Item Specifications

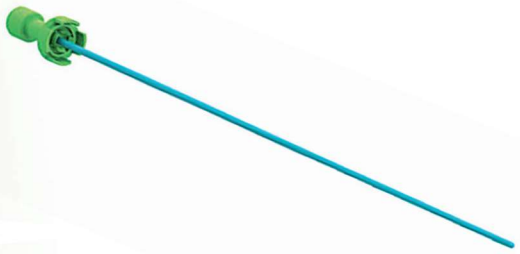
Inner diameter	Sheath length	Item reference
4 Fr	7 cm	RS+B40G07SQ
5 Fr	7 cm	RS+B50G07SQ
6 Fr	7 cm	RS+B60G07SQ

Please quote above item reference codes when placing an order

IS616/5GB0616ITI

RADIFOCUS®
OBTURATOR

Introducer Sheath



An obturator supports the wall of the indwelling introducer sheath without a catheter in place.

Product Characteristics

- *Snap-on connection to sheath hub*
- *High flexibility and kink-resistance*
- *Color coded*
- *Made of polypropylene with a rounded tip*

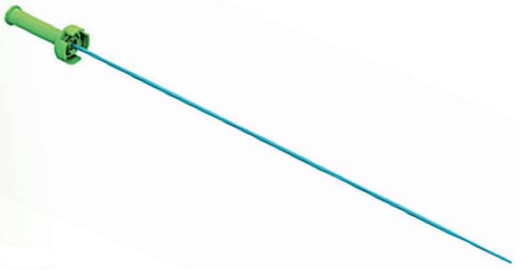
Item Specifications

Compatible Introducer Sheath size	Length	
	10 cm	25 cm
4 Fr	XX*RF050410M	—
5 Fr	XX*RF050510M	XX*RF050525M
6 Fr	XX*RF050610M	XX*RF050625M
7 Fr	XX*RF050710M	XX*RF050725M
8 Fr	XX*RF050810M	XX*RF050825M
9 Fr	XX*RF050910M	—

Please quote above item reference codes when placing an order

RADIFOCUS®
VESSEL DILATOR

Introducer Sheath



A vessel dilator facilitates the pre-dilatation of puncture site.

Item Specifications

Outer diameter	Length	Guidewire compatibility	
		0.035" (0.89 mm)	0.038" (0.97 mm)
4 Fr	15.5 cm	RF*VD40K10M	—
5 Fr	15.5 cm	RF*VD50K10M	RF*VD50N10M
6 Fr	15.5 cm	RF*VD60K10M	RF*VD60N10M
7 Fr	15.5 cm	RF*VD70K10M	RF*VD70N10M
8 Fr	15.5 cm	RF*VD80K10M	RF*VD80N10M
9 Fr	15.5 cm	RF*VD90K10M	RF*VD90N10M
10 Fr	15.5 cm	RF*VD10K10M	—
11 Fr	15.5 cm	RF*VD11K10M	—

Please quote above item reference codes when placing an order

IS616/GB0616IT1

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

RADIFOCUS® INTRODUCER II
(Transradial Kit)

Product: **Catheter Introducer**
(See Appendix A for related product codes)

declare that the above product of Class IIa is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.1 (a) of the Directive, relating to the "Full Quality Assurance System" set out in Annex II, and by certification of Annex II.3 (Registration No: HD 60106290 0001), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 29.01.2020
(place and date of issue)

M.J. Aerts
VP Regulatory & Quality
TERUMO EUROPE N.V.

Appendix A – Related product codes

The product code is composed of 12 digits maximum and explained as follows:

1	2	3	4	5	6	7	8	9	10	11	12
R	**T**	Radifocus Introducer II Transradial Access									
Production site		**-**	Terumo Europe N.V.								
Indication of kit compostion			**R**	Sheath, Dilator, Spring guide wire and metallic entry needle							
Size of sheath in Fr				**4**	**0**	4 Fr					
				5	**0**	5 Fr					
				6	**0**	6 Fr					
				7	**0**	7 Fr					
Dilator I.D., distal tip length (difference of Dilator / sheath assembly), and type of metallic needle							Difference in length		Dilator I.D.		Metallic entry needle
							A		25		0.018"		22G x 35 mm
							D		25		0.021"		21G x 35 mm
							G		25		0.025"		20G x 35 mm
Length of the sheath							**0**	**7**	70 mm				
							1	**0**	100 mm				
Mini spring guide wire type									**N**	No guide wire			
									P	Straight, fixed core, uncoated, distal end flexible			
Packaging										**Q**	Tray pack (Multi language)		
Special product indication: alphanumerical digit to distinguish from standard items											**X**		

TERUMO

No.DOC-DQ010- 0245/DOC-DQ010-0821

Rev.19

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Introducer II

Product : Catheter Introducer

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 0001), 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 15:34:34 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A - List of Code Number Structure

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

Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) B : Sheath, Dilator, Mini guide wire, (Guide inserter[*2]) C : Sheath, Dilator E : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter[*2]) G : Sheath, Dilator, Mini guide wire, Scalpel[*1] (Guide inserter[*2]) H : Dilator J : Sheath, Dilator, Scalpel[*1] K : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel[*1], (Guide inserter[*2]) L : Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel[*1] M : Sheath, Dilator, Entry needle (SurfloFlash), Scalpel[*1] N : Sheath, Dilator, Mini guide wire, Syringe, Scalpel[*1], (Guide inserter[*2]) P : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter[*2]) Q : Dilator, Mini guide wire, (Guide inserter[*2]) R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter[*2]) S : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) W : Mini guide wire [*1]: not contained in the export specifications [*2]: contained when the mini guide wire has an angled tip or a J tip.

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>5-6</td><td>Sheath Size (w/o hydrophilic polymer coating)
Characters: 40 45 50 55 60 65 70 75 80 85 90 10 11 00
Size: 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0 11.0 no sheath
Sheath Size (with hydrophilic polymer coating)
Characters: F4 F5 F6 F7
Size: 4.0 5.0 6.0 7.0</td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>a-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">Standard</td></tr>
<tr><td>b-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>a-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">With adapter</td></tr>
<tr><td>b-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>---</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table>
Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM):
<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="5">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.018”</td><td>0.021”</td><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td rowspan="4">Type of scalpel and tray</td><td>a-type</td><td>A</td><td>D</td><td>G</td><td>K</td><td>N</td><td rowspan="2">With adapter</td></tr>
<tr><td>b-type</td><td>B</td><td>E</td><td>H</td><td>L</td><td>P</td></tr>
<tr><td>a-type</td><td>C</td><td>F</td><td>J</td><td>M</td><td>Q</td><td rowspan="2">Standard</td></tr>
<tr><td>b-type</td><td>V</td><td>W</td><td>X</td><td>Y</td><td>Z</td></tr>
<tr><td colspan="2">Entry needle size</td><td>22G×1”</td><td>22G×1”</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td colspan="2">metallic needle size</td><td>---</td><td>Metallic Entry Needle improved product 21G×1 2/5”</td><td>Metallic Entry Needle improved product 20G×1 2/5”</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table></td></tr>
</table>

Character number	Characters & Meaning
8-9	Length of sheath 00 : no sheath 05～ : 50mm～
10	Type of mini guide wire A: Plastic, Angled B: Plastic, Angled, 4mm of tip cut E: Straight E F: Flex, Angled H: Short tapered, short angle J: Plastic, 3mm J K: Stiff, Angled M: Spring, J N: No mini guide wire contained. P: Spring, Straight S: Plastic, Straight V: Plastic, 1.5mm J-angle Y: Flex, Straight
11	Packaging Q: Tray package (Multi-language) R: Pouch package (Multi-language)
12	Reserved 1: With scalpel. 5: Inner diameter of dilator at distal end: 0.038”, Outer diameter of mini guide wire: 0.035” Z: Entry needle: 20Gx2”→20Gx1 1/4” Length of mini guide wire: 80cm→45cm, scalpel contained. W: Entry needle: 20Gx1 1/4”, scalpel contained.

Appendix A - List of Code Number Structure

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

<table>
<tr><th>Character number</th><th>Characters & Meaning</th></tr>
<tr><td>1, 2</td><td>Product name
RS: Introducer kit</td></tr>
<tr><td>3</td><td>Destination
+ / ＊: Manufactured by TVC for worldwide excluding Japan</td></tr>
<tr><td>4</td><td>Kit contents
A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel, (Guide inserter*)
B : Sheath, Dilator, Mini guide wire, (Guide inserter*)
C : Sheath, Dilator
R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle), (Guide inserter*)
*: contained when the mini guide wire has an angled tip or a J tip.</td></tr>
<tr><td>5-6</td><td>Sheath Size (Fr) (w/o hydrophilic polymer coating)
<table>
<tr><td>Characters</td><td>40</td><td>50</td><td>60</td><td>70</td><td>80</td></tr>
<tr><td>Size</td><td>4.0</td><td>5.0</td><td>6.0</td><td>7.0</td><td>8.0</td></tr>
</table></td></tr>
<tr><td>7</td><td>Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
<table>
<tr><td rowspan="2"></td><td colspan="3">Mini guide wire diameter/ Dilator inner diameter</td><td rowspan="2">Type of Surflo</td></tr>
<tr><td>0.025”</td><td>0.035”</td><td>0.038”</td></tr>
<tr><td>Type of scalpel and tray</td><td>G</td><td>K</td><td>N</td><td>Standard</td></tr>
<tr><td>Entry needle size</td><td>20G×2”</td><td>18G×2 1/2”</td><td>16G×2 1/2”</td><td></td></tr>
<tr><td>metallic needle size</td><td>---</td><td>18G×2 3/4”</td><td>18G×2 3/4”</td><td></td></tr>
</table></td></tr>
<tr><td>8-9</td><td>Length of sheath
00 : no sheath0
5～ : 50mm～</td></tr>
<tr><td>10</td><td>Type of mini guide wire
A: Plastic, Angled
M: Spring, J
N: No mini guide wire contained.
P: Spring, Straight
S: Plastic, Straight</td></tr>
<tr><td>11</td><td>Packaging
Q: Tray package (Multi-language #, Chinese)
R: Pouch package (Multi-language #, Chinese)</td></tr>
<tr><td>12</td><td>Reserved
1: With scalpel.
5: Inner diameter of dilator at distal end: 0.038”,
Outer diameter of mini guide wire: 0.035”
Z: Entry needle: 20Gx2”→20Gx1 1/4”
Length of mini guide wire: 80cm→45cm, scalpel contained.</td></tr>
</table>

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

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III 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.

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

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Deutsche
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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
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Tillystraße 2 · 90431 Nürnberg · Germany

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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

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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

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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

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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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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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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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:

/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

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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