

AGENȚIA MEDICAMENTULUI  
ȘI DISPOZITIVELOR MEDICALE

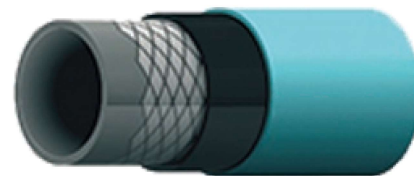
## REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declarație de conformitate CE
I.3. Certificatul CE	Certificat CE_Design Examination
I.3. Certificatul CE	Certificat CE_Full Quality Assurance

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		glidecath								
DM000258185	CATETER DE DIAGNOSTIC PENTRU ANGIOGRAFIE	Radifocus® Glidecath®	RF*ZRV411CJM	RF*ZRV411CJM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000313	09-12-2019	
DM000258187	CATETER DE DIAGNOSTIC PENTRU ANGIOGRAFIE	Radifocus® Glidecath®	RF*ZUF4115JM	RF*ZUF4115JM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000313	09-12-2019	
DM000258184	CATETER DE DIAGNOSTIC PENTRU ANGIOGRAFIE	Radifocus® Glidecath®	RF*ZRV411CM	RF*ZRV411CM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000313	09-12-2019	
DM000258186	CATETER DE DIAGNOSTIC PENTRU ANGIOGRAFIE	Radifocus® Glidecath®	RF*ZUF411CJM	RF*ZUF411CJM	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000313	09-12-2019	
DM000240316	CATETER DE DIAGNOSTIC PENTRU ANGIOGRAFIE	Radifocus® Glidecath®	4Fr x 100cm Simmons/Sidewir 2 SH0	1RFWA24110M	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	Rg04-000259	17-10-2019	
DM000240264	CATETER DE DIAGNOSTIC PENTRU ANGIOGRAFIE	Radifocus® Glidecath®	4Fr x 100cm Bentson- Hanafée-Wilson 2 SH0	2RFWE24110M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000259	17-10-2019	
DM000240227	CATETER DE DIAGNOSTIC PENTRU ANGIOGRAFIE	Radifocus® Glidecath®	5Fr x 100cm Simmons/Sidewir 2 SH0	2RFYA25110M	Belgia	TERUMO EUROPE N.V.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000259	17-10-2019	





## Angiographic Catheter

Radifocus Angiographic Catheter is a 5 Fr angiographic catheter intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guidewire or a catheter into the target site.



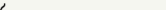
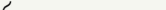
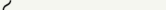
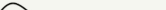
### Product Characteristics

- Polyamide surface, rounded tip and one-piece body structure.
- Internal metallic mesh braid.
- Radiopaque surface.
- High pressure resistance (up to 1000 psi/6895 kPa).
- Various type shapes available.

### General specifications



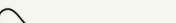
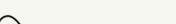
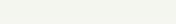
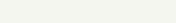


<b>Catheter Material</b>	Polyamide
<b>Guidewire Compatibility - Diameter</b>	0.038 in / 0.97 mm
<b>Hydrophilic Coating</b>	Polyamide
<b>Inner Diameter</b>	0.043 in / 1.1 mm
<b>Mesh Braid Material</b>	Stainless Steel
<b>Pressure Limit</b>	1000 psi / 6895 kPa

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	65 cm	Femoral - Cerebral Shape	 Vertebral	0	RF-EH1500GM
5 Fr 1.7 mm	65 cm	Femoral - Ventricular Shape	-	6	RF-FG1500GM
5 Fr 1.7 mm	65 cm	Femoral - Ventricular Shape	 Straight	6	RF-FK1500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF-DD4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF*DD4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF-DD6500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF-DD5500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Shepherd Hook 0.8 cm	0	RF-DC3500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Shepherd Hook 1.0 cm	0	RF*DC4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Shepherd Hook 1.0 cm	0	RF-DC4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 2 Middle	0	RF-DB5500GM




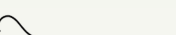

Please quote above item reference codes when placing an order

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 2 Middle	2	RF-DB2500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 2 Middle	2	RF*DB2500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 3 Large	0	RF-DB6500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 3 Large	2	RF-DB3500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 1 Small	0	RF-DB4500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	 Cobra 1 Small	2	RF-DB1500GM
5 Fr 1.7 mm	65 cm	Femoral - Visceral Shape	-	0	RF-DE4500GM
5 Fr 1.7 mm	80 cm	Femoral - Ventricular Shape	-	6	RF-FG15008M
5 Fr 1.7 mm	80 cm	Femoral - Ventricular Shape	 Straight	6	RF*FK15008M
5 Fr 1.7 mm	80 cm	Femoral - Ventricular Shape	 Straight	6	RF-FK15008M


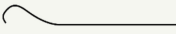
Please quote above item reference codes when placing an order

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF-DAC5008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF-DA25008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF*DG35008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	0	RF-DAB5008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	2	RF*DA15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	2	RF-DA15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	-	4	RF*FL15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Straight	0	RF*DI15008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 2 Middle	0	RF*DB55008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 2 Middle	0	RF-DB55008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 3 Large	0	RF-DB65008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 3 Large	0	RF*DB65008M






Please quote above item reference codes when placing an order

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 1 Small	0	RF-DB45008M
5 Fr 1.7 mm	80 cm	Femoral - Visceral Shape	 Cobra 1 Small	0	RF*DB45008M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EJ15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EB35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EB15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EC25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EC45010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EA15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EA25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EA35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EC25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EB15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EB25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EJ15010M


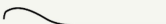
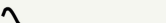
Please quote above item reference codes when placing an order

Item specifications

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EC35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EA15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF-EA25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EB25010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EC45010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	-	0	RF*EA35010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Vertebral	0	RF-EH15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Vertebral	0	RF*EH15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Vertebral	2	RF-EH45010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Bentson-Hanafee- Wilson 1	0	RF-EE15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 MANI	0	RF*EG15010M

Please quote above item reference codes when placing an order

*Item specifications*

Outer Diameter	Length	Product Type	Shape	Side Holes	Code
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 MANI	0	RF-EG15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Newton technique 1	0	RF-EC15010M
5 Fr 1.7 mm	100 cm	Femoral - Cerebral Shape	 Bentson-Hanafee- Wilson 2	0	RF-EE25010M
5 Fr 1.7 mm	100 cm	Femoral -Cerebral Shape	-	0	RF-EA45010M
5 Fr 1.7 mm	110 cm	Femoral - Ventricular Shape	-	6	RF-FG15011M
6 Fr 2.0 mm	80 cm	Femoral - Visceral Shape	-	4	RF*FL16008M



**EC Design-Examination Certificate**  
**Directive 93/42/EEC Annex II, Section 4**  
**Medical Devices**

**Registration No.:** ID 60148569 0001

**Report No.:** 21228431 007

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

**Product Identification:** Radifocus Glidecath  
(see attachment for products included)  
Replaces Certificate, Registration No.: ID 60102630 0001

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:** 2024-05-26

**Effective Date:** 2020-04-21

**Date:** 2020-04-21

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  
Certificate**

**Registration No.:** ID 60148569 0001  
**Report No.:** 21228431 007

**Manufacturer:** Terumo Corporation  
44-1, 2-chome, Hatagaya  
SHIBUYA-KU, TOKYO  
151-0072 JAPAN

**Angiographic Catheter Radifocus Glidecath**

Product code: R F \* □ □ □ □ □ □ □ □ □ □ □ □  
Character number: 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters & Meaning
1-2	Product name RF: Radifocus
3	Destination * : for export
4	Applied region: X: Renal & Visceral, Y: Cerebral (for single braided) Z: Renal & Visceral, W: Cerebral (for double braided)
5-6	Indication of tip configuration: these two digits together with digit 4 makes an unique code specific for each shape and number of side holes
7	Outer diameter of catheter: Indication: 4 5 Diameter (Fr/mm): 4 (1.40) 5 (1.70)
8	Indication of two-way stopcock 1 : without two-way stopcock
9-10	Catheter length
	Character : 02 0C 03 0D 04 0E 05 0F 06 0G 07 Length (cm): 20 25 30 35 40 45 50 55 60 65 70
	Character : 0H 08 0I 09 0J 10 1A 11 1B 12 1C Length (cm): 75 80 85 90 95 100 105 110 115 120 125
	Character : 13 1D 14 1E 15 Length (cm): 130 135 140 145 150

Date 2020-04-21



**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** ID 60148569 0001  
**Report No.:** 21228431 007


**Manufacturer:** Terumo Corporation  
44-1, 2-chome, Hatagaya  
SHIBUYA-KU, TOKYO  
151-0072 JAPAN

**Angiographic Catheter Radifocus Glidecath**

Product code: R F \* □ □ □ □ □ □ □ □ □ □ □ □ □ □  
Character number: 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters & Meaning
11	<p>Hydrophilic coating length</p> <p>Character : 1 2 3 4 5 6 7 8 9 F G</p> <p>Length (cm): 1 2 3 4 5 6 7 8 9 20 25</p> <p>Character : H I J K L</p> <p>Length (cm): 30 35 40 45 50</p> <p>The eleventh character is omitted for all catheters with hydrophilic coating length of 15 cm.</p>
12	<p>Language for labeling</p> <p>M = Multilanguage</p> <p>A = Multilanguage (sold in USA)</p>

Date 2020-04-21



**Notified Body**

**TÜVRheinland**

*S. Pane*

**Dipl.-Ing. S. Pane**

## DECLARATION OF CONFORMITY

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

being the manufacturer of:

### **RADIFOCUS<sup>®</sup>**


### **ANGIOGRAPHIC CATHETER**

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

declare that the above product of Class III 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) and Annex II.4 (Registration No: ID 60114889 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, 15.01.2019

(place and date of issue)



M.J. Aerts

VP Quality and Regulatory  
Affairs

TERUMO EUROPE N.V.

### Appendix A – Related product codes

The product code is composed of 11 digits maximum and explained as follows:

1	2	3	4	5	6	7	8	9	10	11	
<b>R</b>	<b>F</b>	RadiFocus									
<b>Production site</b>	-	Terumo Europe									
<b>Indication of catheter use &amp; structure</b>	<b>D</b>	Renal & Visceral use									
	<b>E</b>	Cerebral									
	<b>F</b>	Cardiac									
<b>Indication of tip configuration</b>			Tip shape				Tip curve length		Side holes		
	<b>D In position 4</b>										
	<b>A</b>	<b>1</b>	Femoral-Visceral RENAL				-	2			
	<b>A</b>	<b>2</b>	Femoral-Visceral RENAL				-	None			
	<b>A</b>	<b>4</b>	Femoral-Visceral Cobra Kimoto Type				Small	None			
	<b>A</b>	<b>7</b>	Modified RENAL				-	None			
	<b>A</b>	<b>8</b>	Femoral-Visceral Cobra				Small	1			
	<b>A</b>	<b>B</b>	Femoral-Visceral RENAL Right (small curve)				-	None			
	<b>A</b>	<b>C</b>	Femoral-Visceral RENAL Left				-	None			
	<b>B</b>	<b>1</b>	Femoral-Visceral COBRA				Small	2			
	<b>B</b>	<b>2</b>	Femoral-Visceral COBRA				Middle	2			
	<b>B</b>	<b>3</b>	Femoral-Visceral COBRA				Large	2			
	<b>B</b>	<b>4</b>	Femoral-Visceral COBRA				Small	None			
	<b>B</b>	<b>5</b>	Femoral-Visceral COBRA				Middle	None			
	<b>B</b>	<b>6</b>	Femoral-Visceral COBRA				Large	None			
	<b>B</b>	<b>7</b>	Femoral-Visceral Cobra				Small	2			
	<b>B</b>	<b>8</b>	Femoral-Visceral Cobra				Middle	2			
	<b>B</b>	<b>9</b>	Femoral-Visceral Cobra				Large	2			
	<b>C</b>	<b>1</b>	Femoral-Visceral Shepherd Hook				0.8 cm	2			
	<b>C</b>	<b>2</b>	Femoral-Visceral Shepherd Hook				1.0 cm	2			
	<b>C</b>	<b>3</b>	Femoral-Visceral Shepherd Hook				0.8 cm	None			
	<b>C</b>	<b>4</b>	Femoral-Visceral Shepherd Hook				1.0 cm	None			
	<b>C</b>	<b>6</b>	Femoral-Visceral Shepherd Hook				1.2 cm	None			
	<b>C</b>	<b>7</b>	Femoral-Visceral Shepherd Hook				CJ1	None			
	<b>C</b>	<b>8</b>	Femoral-Visceral Shepherd Hook				CJ2	1			
	<b>D</b>	<b>3</b>	Femoral-Visceral J Curve				Small	2			
	<b>D</b>	<b>4</b>	Femoral-Visceral J-Curve				1	None			
	<b>D</b>	<b>5</b>	Femoral-Visceral J-Curve				2	None			
	<b>D</b>	<b>6</b>	Femoral-Visceral J-Curve				3	None			
	<b>D</b>	<b>8</b>	Femoral-Visceral J Curve				4 cm	None			
	<b>E</b>	<b>1</b>	Femoral-Visceral Sidewinder				1	2			
	<b>E</b>	<b>2</b>	Femoral-Visceral Sidewinder				2	2			
	<b>E</b>	<b>3</b>	Femoral-Visceral Sidewinder				3	2			
<b>E</b>	<b>4</b>	Femoral-Visceral Sidewinder				1	None				
<b>E</b>	<b>5</b>	Femoral-Visceral Sidewinder				2 cm	None				
<b>E</b>	<b>6</b>	Femoral-Visceral Sidewinder				3 cm	None				
<b>F</b>	<b>1</b>	Femoral-Visceral Mikaelsson				1	None				
<b>F</b>	<b>2</b>	Femoral-Visceral Mikaelsson				2	None				
<b>F</b>	<b>3</b>	Femoral-Visceral Mikaelsson				3	None				
<b>G</b>	<b>1</b>	Femoral-Visceral RLG				-	None				
<b>G</b>	<b>2</b>	Femoral-Visceral RDP				-	None				
<b>H</b>	<b>1</b>	Femoral-Visceral Shepherd Hook Modified				15.0 mm	1				
<b>H</b>	<b>2</b>	Femoral-Visceral Shepherd Hook Modified				17.5 mm	1				

1	2	3	4	5	6	7	8	9	10	11
<b>Indication of tip configuration (continued)</b>	<b>H</b>	<b>3</b>			Femoral-Visceral Shepherd Hook Modified	20.0 mm				1
	<b>H</b>	<b>4</b>			Femoral-Visceral Shepherd Hook Modified	30.0 mm				1
	<b>L</b>	<b>1</b>			Femoral-Visceral JA	1				None
	<b>N</b>	<b>3</b>			Femoral-Visceral Hook T	3				1
	<b>N</b>	<b>6</b>			Femoral-Visceral Hook R	-				1
	<b>N</b>	<b>8</b>			Femoral-Visceral Hook	AGC				None
	<b>N</b>	<b>9</b>			Femoral-Visceral Kyuudai Type	-				-
	<b>O</b>	<b>1</b>			Femoral-Visceral Hirai Type	-				None
	<b>O</b>	<b>4</b>			Femoral-Visceral Hook 10	-				None
	<b>O</b>	<b>5</b>			Femoral-Visceral Nagatomi Type	1				None
	<b>O</b>	<b>6</b>			Femoral-Visceral Nagatomi Type	2				None
	<b>P</b>	<b>1</b>			Femoral-Visceral LG	-				None
	<b>P</b>	<b>4</b>			Femoral-Visceral Yamawaki-R	-				None
	<b>Q</b>	<b>1</b>			Femoral-Visceral GT	1				None
	<b>Q</b>	<b>2</b>			Femoral-Visceral GT	1				2
	<b>Q</b>	<b>7</b>			Femoral-Visceral NCC	-				None
	<b>S</b>	<b>1</b>			Femoral-Visceral Hiramatsu	1				None
	<b>S</b>	<b>7</b>			Femoral-Visceral Shepherd Hook KT Type	-				1
	<b>S</b>	<b>8</b>			Femoral-Visceral Shepherd Hook KK Type	-				1
	<b>T</b>	<b>1</b>			Femoral-Visceral J Curve	Large				1
	<b>T</b>	<b>7</b>			Femoral-Visceral J Curve Short tip	Large				None
	<b>V</b>	<b>2</b>			Femoral-Visceral LAV	55 mm				None
	<b>E In position 4</b>									
	<b>A</b>	<b>1</b>			Femoral-Cerebral Simmons	1				None
	<b>A</b>	<b>2</b>			Femoral-Cerebral Simmons	2				None
	<b>A</b>	<b>3</b>			Femoral-Cerebral Simmons	3				None
	<b>A</b>	<b>4</b>			Femoral-Cerebral Simmons	4				None
	<b>B</b>	<b>1</b>			Femoral-Cerebral Headhunter	1				None
	<b>B</b>	<b>2</b>			Femoral-Cerebral Headhunter	3				None
	<b>B</b>	<b>3</b>			Femoral-Cerebral Headhunter	4				None
	<b>B</b>	<b>4</b>			Femoral-Cerebral Hilal Modified Headhunter	H1H				None
	<b>B</b>	<b>6</b>			Femoral-Cerebral Hilal Modified Headhunter	H5H				None
	<b>B</b>	<b>7</b>			Femoral-Cerebral Hilal Modified Headhunter	H6H				None
	<b>B</b>	<b>8</b>			Femoral-Cerebral Hilal Modified Headhunter	H1P				None
	<b>C</b>	<b>1</b>			Femoral-Cerebral Newton Technique	1				None
	<b>C</b>	<b>2</b>			Femoral-Cerebral Newton Technique	2				None
	<b>C</b>	<b>3</b>			Femoral-Cerebral Newton Technique	3				None
	<b>C</b>	<b>4</b>			Femoral-Cerebral Newton Technique	4				None
	<b>C</b>	<b>5</b>			Femoral-Cerebral Newton Technique	5				None
	<b>C</b>	<b>9</b>			Femoral-Cerebral K Special	-				None
	<b>D</b>	<b>1</b>			Femoral-Cerebral Harwood-Nash	1				None
	<b>E</b>	<b>1</b>			Femoral-Cerebral Bentson-Hanafee-Wilson	1				None
	<b>E</b>	<b>2</b>			Femoral-Cerebral Bentson-Hanafee-Wilson	2				None
	<b>E</b>	<b>3</b>			Femoral-Cerebral Bentson-Hanafee-Wilson 3	JB3				None
	<b>E</b>	<b>9</b>			Femoral-Cerebral Kameyana	-				None
	<b>F</b>	<b>1</b>			Femoral-Cerebral Kerber	-				None
	<b>F</b>	<b>8</b>			Femoral-Cerebral Bentson-Hanafee-Wilson 2 Modified	JB2				None
	<b>G</b>	<b>1</b>			Femoral-Cerebral Mani	-				None
	<b>H</b>	<b>1</b>			Femoral-Cerebral Vertebral	-				None
	<b>H</b>	<b>4</b>			Femoral-Cerebral Vertebral	-				2
	<b>J</b>	<b>1</b>			Femoral-Cerebral Hinck	1				None
	<b>J</b>	<b>2</b>			Femoral-Cerebral Hinck	2				None
	<b>K</b>	<b>1</b>			Femoral-Cerebral Niigata Type	1				None
	<b>K</b>	<b>2</b>			Femoral-Cerebral Niigata Type	2				None

1	2	3	4	5	6	7	8	9	10	11				
<b>Indication of tip configuration (continued)</b>				<b>L</b>	<b>1</b>	Femoral-Cerebral Berenstein				-	None			
				<b>L</b>	<b>3</b>	Femoral-Cerebral Berenstein Komonji Type				-	2			
				<b>F in position 4</b>										
				<b>G</b>	<b>1</b>	Femoral-Ventricular Pigtail				-	6			
				<b>K</b>	<b>1</b>	Femoral-Ventricular Straight				-	6			
<b>Outer diameter of catheter</b>						<b>5</b>	5 Fr. / 1.70 mm							
<b>Indication of stopcock</b>							<b>0</b>	Without Two-way stopcock						
<b>Catheter length</b>								<b>0</b>	<b>G</b>	65 cm				
								<b>0</b>	<b>7</b>	70 cm				
								<b>0</b>	<b>8</b>	80 cm				
								<b>0</b>	<b>9</b>	90 cm				
								<b>1</b>	<b>0</b>	100 cm				
								<b>1</b>	<b>1</b>	110 cm				
<b>Packaging indication</b>								Multilingual		<b>M</b>				

# Certificate

## 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



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



# Certificate



## 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  
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# Certificate

## 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<br>Ludwig-Erhard-Str. 6<br>65760 Eschborn<br>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.<br>Bâtiment Renaissance, 3 rond-point des Saules<br>Guyancourt<br>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.<br>Via Paolo di Dono 73<br>00142 Roma<br>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<br>Avda. Juan Carlos I, N°13-7 Planta<br>28806 Alcalá de Henares (Madrid)<br>Spain | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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# Certificate



## 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.<br>Otium House<br>2 Freemantle Road<br>Bagshot<br>Surrey<br>GU19 5LL<br>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.<br>Benelux Sales Division<br>Interleuvenlaan 40<br>3001 Leuven<br>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<br>Sven Källfets gata 16<br>SE-426 71 Västra Frölunda<br>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<br>Zweigniederlassung Switzerland<br>Bodenackerstrasse 3<br>8957 Spreitenbach<br>Switzerland | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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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.<br>European Distribution Center<br>Brikkenovenstraat 48<br>3600 Genk<br>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.<br>Terumo Interventional Systems<br>EMEA (TIS-EMEA)<br>Interleuvenlaan 40<br>3001 Leuven<br>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.<br>Terumo Cardiovascular Europe<br>Middle East & Africa (TCV-EMEA)<br>Ludwig-Erhard-Straße 6<br>65760 Eschborn<br>Germany | Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices                |

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# Certificate



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

Report No.: 3350367-50  
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# Certificate



## 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.<br>Emerging Market Division<br>Interleuvenlaan 40<br>3001 Leuven<br>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<br>Wisniowy Business Park budynek D<br>ul. 1 Sierpnia 6<br>02-134 Warszawa<br>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  
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Dipl.-Ing. (FH) D. Wiedemuth  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



**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.

**Effective Date:** 2020-04-21

**Date:** 2020-04-21

Notified Body

  
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.

**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

**Date:** 2020-04-21

**Notified Body**



*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**



**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

**Date:** 2020-04-21

Notified Body



*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**