EC Certificate

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

Registration No.: HD 60145252 0001

Report No.: 12031336 018

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

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

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

Effective Date: 2019-12-23

Date: 2019-12-23

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

M.Aihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

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

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 023

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
- Portable insulin infusion pump
- Portable insulin infusion administration set

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

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.

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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® Prüfzertifizierungsstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

EC Design-Examination Certificate

Directive 93/42/EEC Annex II, Section 4

Medical Devices

Registration No.: ID 60156557 0001

Report No.: 21262066 005

Manufacturer:

TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Product Identification:

Radifocus Guide Wire M

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60116053 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: 2021-05-14

Date: 2021-05-14

Notified Body

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. S. Pane

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: ID 60156557 0001
Report No.: 21262066 005

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

Scope: Radifocus Guide Wire M

Product Code System

Radifocus Guide Wire M

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

Position	Indication & Meaning
1 - 2	Product group: RF : Radifocus
3	Manufacturing site: -: TERUMO Europe N.V.
4	Core wire flexibility: G : Standard P : Stiff
5	Tip configuration: A : Angled S : Straight
6-7	Outer diameter of guide wire

Indication	18	25	32	35	38
Diameter (inch)	0,018" (0,020")*	0,025"	0,032"	0,035"	0,038"
(mm)	0,46 mm (0,51 mm)*	0,64 mm	0,81 mm	0,89 mm	0,97 mm

* for stiff-core type

8-9 Guide wire length:

Indication:	05	08	12	15	18	22	26	30	40	45
Length (cm)	50	80	120	150	180	220	260	300	400	450

10 Flexible part length:

Indication:	1	3	5	8
Length (cm)	1	3	5	8

11	Languages used for indication: M : Multi-language
12	Special product indication: alphanumerical digit to distinguish from standard items

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierung

Date : 2021-05-14

Dipl.-Ing. S. Pane

TERUMO

No.DOC-DQ010-0203 / DOC-DQ010-0837
Rev.18

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS Guide Wire M

Product : Catheter Guide Wire

declare that the above products of **Class III** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 (Registration No.: HD 60145252 0001), and Annex II, Section 4 (Registration No.: ID 60156558 0001) under the supervision of TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

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

Object of the declaration: see appendix A

Tokyo, June 3, 2021
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Appendix A - List of Code Number Structure

RADIFOCUS GUIDEWIRE M Product code system

1) Without radiopaque tip marker
Standard type

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

Character number	Denotation						
1-2	Product name	RADIFOCUS GUIDE WIRE M					
3	Destination	＊: for export					
4	Core wire flexibility	**G** : Standard **H** : Half stiff **P** : Stiff					
5	Tip configuration	**A** : Angled **B** : J-angled (3mm) **C** : J-angled (6mm) **E** : Double-angled **N** : J-angled (2mm) **R** : J-angled (1.5mm) **S** : Straight					
6-7	Outer diameter of guide wire	**18**				**25**	
		stiff-core type: 0.020" other core types: 0.018"				0.025"	
		32		**35**		**38**	
		0.032"		0.035"		0.038"	
8-9	Guide wire length	**05**	**07**	**08**	**12**	**15**	**18**
		50 cm	70 cm	80 cm	120 cm	150 cm	180 cm
		22	**26**	**30**	**35**	**40**	**45**
		220 cm	260cm	300cm	350cm	400 cm	450 cm
10	Flexible part length in the distal tip	**1** : 1cm (short taper) **3** : 3cm (normal taper) **5** : 5cm (long taper) **8** : 8cm (long long taper)					
11	Languages used for the indications	M : Multilanguage					

High Flex Type

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

Character number	Denotation								
1-2	Product name	RADIFOCUS GUIDE WIRE M							
3	Destination	*: for export							
4	Core wire flexibility	**G** : Standard **H** : Half stiff							
5	Tip configuration	**J** : Straight **F** : Angled							
6-7	Outer diameter of guide wire	**18**	**25**	**32**	**35**	**38**			
		0.018"	0.025"	0.032"	0.035"	0.038"			
8-9	Guide wire length	**12**	**15**	**18**	**22**	**26**	**30**	**40**	**45**
		120cm	150cm	180cm	220cm	260cm	300cm	400cm	450cm
10	Flexible part length in the distal tip	**3** : 3cm (normal taper)							
11	Languages used for the indications	**M** : Multilanguage							

Super-Flex Type

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

Character number	Denotation				
1-2	Product name	RADIFOCUS GUIDE WIRE M			
3	Destination	*: for export			
4	Core wire flexibility	**G** : Standard			
5	Tip configuration	**V** : J-angled (2mm)			
6-7	Outer diameter of guide wire	**35**: 0.035"			
8-9	Guide wire length	**15**	**18**	**20**	**22**
		150 cm	180 cm	200 cm	220 cm
10	Flexible part length in the distal tip	**1** : 1cm (short taper)			
11	Languages used for the indications	M : Multilanguage			

Shapeable Type (E Type)

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

Character number	Denotation					
1-2	Product name	RADIFOCUS GUIDE WIRE M				
3	Destination	*: for export				
4	Core wire flexibility	**G** : Standard				
5	Tip configuration	**L** : Straight **K** : Angled				
6-7	Outer diameter of guide wire	**18**	**25**	**32**	**35**	**38**
		0.018"	0.025"	0.032"	0.035"	0.038"
8-9	Guide wire length	**12**	**15**	**18**	**22**	**26**
		120cm	150cm	180cm	220cm	260cm
10	Flexible part length in the distal tip	**3** : 3cm (normal taper)				
11	Languages used for the indications	M : Multi-language				

2) With radiopaque tip marker

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

Character number	Denotation				
1, 2, 4	Product name	RADIFOCUS GUIDE WIRE M			
3	Destination	*: for export			
5	Tip configuration (Angled)	**A** : 45° **B** : 70°			
6-7	Outer diameter of guide wire	**10**	**14**	**16**	**18**
		0.011"	0.014"	0.016"	0.018"
8-9	Guide wire length	**18** : 180cm			
10	Flexible part length in the distal tip	**8** : 8cm (long long taper)			
11	Accessory supplied with the guide wire	**T** : Torque device			
12	Languages used for the indications	**M** : Multilanguage			

RADIFOCUS GUIDEWIRE M manufactured by TVC Product code system

Standard type

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

Position	Meaning of indication						
1-2	Product type	RADIFOCUS GUIDE WIRE M					
3	Destination	+/ * for worldwide excluding Japan					
4	Core wire flexibility	**G** : Standard **H** : Half stiff **P** : Stiff					
5	Tip configuration	**A** : Angled **S** : Straight					
6-7	Outer diameter of guide wire	**18**				**25**	
		stiff-core type: 0.020" / 0.51 mm other core types: 0.018" /0.46 mm				0.025" / 0.64 mm	
		32		**35**		**38**	
		0.032" / 0.81 mm		0.035" / 0.89 mm		0.038" /0.97 mm	
8-9	Guide wire length	**05**	**08**	**12**	**15**	**18**	**22**
		50 cm	80 cm	120 cm	150 cm	180 cm	220 cm
		26					
		260cm					
10	Flexible part length in distal tip	**1** : 1cm (short taper) **3** : 3cm (normal taper) **5** : 5cm (long taper) **8** : 8cm (long long taper)					
11	Languages used for the indications	M : Multilanguage					

DECLARATION OF CONFORMITY

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

being the manufacturer of:

RADIFOCUS® GUIDE WIRE M

Product: **Guide Wire 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 60134707 0001) and Annex II.4 (Registration No: ID 60156557 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, 12.10.2022
(place and date of issue)

K. Verhaert
Vice President Quality,
Regulatory and Vigilance
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	**F**	RadiFocus									
Production site		**-**	Terumo Europe N.V.								
Core wire flexibility			**G**	Standard							
			P	Stiff							
Tip configuration				**A**	Angled						
				S	Straight						
Outer diameter of guide wire					**1**	**8**	0.018" / 0.46 mm				
					1	**8**	0.020" / 0.51 mm (only for stiff type)				
					2	**5**	0.025" / 0.64 mm				
					3	**2**	0.032" / 0.81 mm				
					3	**5**	0.035" / 0.89 mm				
					3	**8**	0.038" / 0.97 mm				
Guide wire length							**0**	**5**	50 cm		
							0	**8**	80 cm		
							1	**2**	120 cm		
							1	**5**	150 cm		
							1	**8**	180 cm		
							2	**2**	220 cm		
							2	**6**	260 cm		
							3	**0**	300 cm		
							4	**0**	400 cm		
							4	**5**	450 cm		
Flexible part length									**1**	1 cm	
									3	3 cm	
									5	5 cm	
									8	8 cm	
Languages used for indication										**M**	Multi-language
Special product indication: alphanumerical digit to distinguish from standard items											**X**