

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

Registration No.: ID 60116053 0001

Report No.: 21262066 001

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 60042797 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: 2021-12-20

Effective Date: 2016-12-21

Date: 2016-12-19

Notified Body



[Signature]
Dr. H. Lüdemann

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 60116053 0001
Report No.: 21262066 001

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

Scope: Radifocus Guide Wire M

Product Code System

Radifocus Guide Wire M

R	F	-	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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: alphanumeric digit to distinguish from standard items										

Date 19.12.2016

H. Lüdemann
Dr. H. Lüdemann

