

**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



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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  
 Dipl.-Ing. S. Pene