

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

Registration No.: ID 60149172 0001

Report No.: 21257349 004

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

Product Identification: Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60114893 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: 2020-05-07

Date: 2020-05-07



Dipl.-Ing. S. Pape

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 60149172 0001
Report No.: 21257349 004

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

Radifocus Optitorque

Product code system

Thoracic use

R H +/* □ □ □ □ □ □ □ □ □ □ □ □
1 2 3 4 5 6 7 8 9 10 11 12

Position	Characters & Meaning
1-2	Product type RH: Radifocus® Optitorque™
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) +/*: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co.,Ltd)
4	Outer diameter of catheter Character: 4 5 6 Diameter: 4 Fr.(1.40 mm) 5 Fr.(1.70 mm) 6 Fr.(2.00 mm)
5-8	Tip shape: 4 alphanumerical digits
9	Number of side holes Character: 0 1 2 4 6 8 Number: 0 1 2 4 6 8
10	Catheter Length Character: 4 E 5 F 6 G 7 H 8 I 9 Length(cm): 40 45 50 55 60 65 70 75 80 85 90 Character : J 0 K 1 L 2 N Length(cm): 95 100 105 110 115 120 125 * The maximum catheter length for the following tip shapes is 100 cm: 3D-Right Modified and 3D RC
11	Braid cut length: Q: 60 mm (For products whose braid cut length is not 60mm, the product code consists of 11 characters and the 11th character denotes the language for labelling)
12	Languages used for the indications M: Multi-language



Date 2020-05-07



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

Attachment to certificate

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

Radifocus Optitorque

Visceral and Cerebral use

R H +/*
1 2 3 4 5 6 7 8 9 10 11

Position	Characters & Meaning
1-2	Product type RH: Radifocus® Optitorque™
3	Destination * : for worldwide excluding Japan (Manufactured by Terumo Co. Ashitaka factory) +/*: for worldwide excluding Japan and U.S.A (Manufactured by Terumo Vietnam Co.,Ltd)
4	Indication of catheter use: A : visceral use B : cerebral use
5-6	Tip shape: 2 alphanumerical digits
7	Outer diameter of catheter Character: 4 5 Diameter: 4 Fr.(1.40 mm) 5 Fr.(1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Catheter Length Character: 02 03 04 05 06 0G 07 0H 08 0I 09 Length(cm): 20 30 40 50 60 65 70 75 80 85 90 Character: 0J 10 1A 11 1B 12 1C Length(cm): 95 100 105 110 115 120 125
11	Language used for the indications M: Multi-language



Date 2020-05-07