

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

Registration No.: ID 60114894 0001

Report No.: 21255836 001

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

**Product
Identification:**

Catheter, Angiography
RADIFOCUS OPTITORQUE

(see attachment for products included)
Replaces certificate, Registration No.: ID 60041981 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: 2021-11-10

Effective Date: 2016-11-11

Date: 2016-11-09

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
Registration No.: ID 60114894 0001
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Radifocus Optitorque

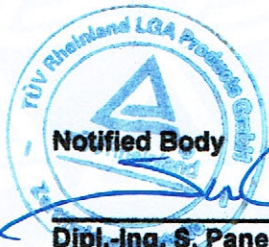
Product code system

(1) Thoracic use

R H - ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
1 2 3 4 5 6 7 8 9 10 11

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Manufacturing site -: TERUMO Europe N.V.
4	Outer diameter of catheter Indication: 4, 5 6 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm); 6 (2.00 mm)
5-8	Tip shape: Character (A~Z, 0~9)
9	Number of side holes Indication: 0 ~ 9 Number of side holes: 0 - 9
10	Catheter Length Indication : 6 G 7 8 9 0 1 Length (cm): 60 65 70 80 90 100 110
11	Language used for the indications M: Multi-language indication

Date, 2016-11-09



Notified Body
Dipl.-Ing. S. Pane

**TÜV Rheinland
LGA Products GmbH
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Radifocus Optitorque

(2) Visceral & Cerebral use

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

Position	Indication & Meaning
1-2	Product name RH: Radifocus® Optitorque™
3	Production site -: TERUMO Europe N.V.
4	Indication of catheter use A : visceral use B : cerebral use
5-6	Tip shape: Character (A~Z, 0~9)
7	Outer diameter of catheter Indication: 4, 5 Size (Fr.): 4 (1.40 mm); 5 (1.70 mm)
8	Availability of stopcock 1 : Without stopcock
9-10	Catheter Length Indication: 02 0G 07 08 09 10 11 Length (cm): 20 65 70 80 90 100 110
11	Languages used for the indication M: Multilanguage

Date, 2016-11-09

