

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

Registration No.: ID 60148413 0001

Report No.: 21228437 006

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

**Product
Identification:**

Outlook

(see attachment for products included)

Replaces Certificate, Registration No.: ID 60102567 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

Notified Body

Effective Date: 2020-04-07

Date: 2020-04-07



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

Doc. 1/2, Rev. 0

Attachment to Certificate

Registration No.: ID 60148413 0001
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Manufacturer: Terumo Corporation
 44-1, 2-chome, Hatagaya
 SHIBUYA-KU, TOKYO 151-0072
 JAPAN

Angiographic Catheter Outlook

<Thoracic use>

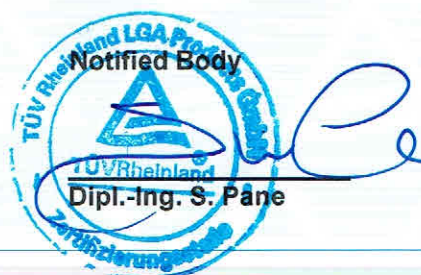
Product code:

Character number:

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

Character number	Characters & Meaning										
1-2	Product type RQ: Outlook										
3	Destination *: for worldwide excluding Japan										
4	Outer diameter of catheter Character : 4 5 Size: Fr. (mm) : 4 (1.40) 5 (1.70)										
5-8	Indication of tip configuration: four digits are specified for each tip shape/Tip curve length										
9	Number of side holes Character : 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, J Number : 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 52										
10	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 P Q R S Length (cm): 95 100 105 110 115 120 125 130 135 140 145 Character : T Length (cm): 150										
11	Spare : 0~9, A~Z If unnecessary, omitted										
12	Language for labeling M: Multi-language										

Date: 2020-04-07



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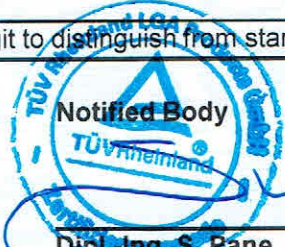
Scope: Angiographic Catheter Outlook

<Visceral and cerebral use>

Product code: R Q ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
 Character number: 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Characters & Meaning
1-2	Product type RQ: Outlook
3	Destination *: for worldwide excluding Japan
4	Indication of catheter use A: Abdominal & Peripheral (Visceral use) B: Cerebral use
5-6	Indication of tip configuration/number of side holes: two digits are specified for each tip shape
7	Catheter size O.D. 4: 4 Fr. (1.40 mm)
8	Availability of stopcock 1 : without stopcock
9-10	Catheter Length Characters : 04 0E 05 0F 06 0G 07 0H 08 0I 09 Length (cm): 40 45 50 55 60 65 70 75 80 85 90 Character : 0J 10 1A 11 1B 12 1C 13 1D 14 1E Length (cm): 95 100 105 110 115 120 125 130 135 140 145 Character : 15 Length (cm): 150
11	Languages used for the indications M: Multilanguage :
12	Special product indication : alphanumerical digit to distinguish from standard items

Date: 2020-04-07


 Notified Body
 TÜVRheinland
 Dipl.-Ing. S. Pane