

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



H. Lüdemann
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

