MED CERT®

Certification. Medical Only.

# EC Certificate of Conformity

**The Notified Body**

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH**
**Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the company:

**TERUMO EUROPE N.V.**
**Interleuvenlaan 40**
**3001 Leuven**
**Belgium**

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

## Annex II without section 4

This certification is subject to surveillance by MEDCERT.

For the placing on the market of class III medical devices covered by this certificate, an additional EC design examination certificate according to Annex II, section 4 of Council Directive 93/42/EEC is required.

**Effective date:** **2019-12-17**
**Expiry date:** **2024-05-27**

Report No.: 3479FS15F
Process No.: QS – 3479
Certificate No.: 3479GB410191217

Hamburg, 2019-12-17

MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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# Appendix of EC Certificate of Conformity

Process No.: QS – 3479
Certificate No.: 3479GB410191217

## List of locations included in the scope of certificate

### Manufacturing site

**Ashitaka Factory of Terumo Corporation**
**150, Maimaigi-cho, Fujinomiya City**
**Shizuoka Prefecture 418-0015**
**Japan**

### Designing site

**Terumo Corporation, R&D Center**
**1500, Inokuchi, Nakai-machi, Ashigarakami-gun,**
**Kanagawa Prefecture 259-0151**
**Japan**

This appendix is integral part of the above-referenced certificate.
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## Appendix of EC Certificate of Conformity

Process No.: QS – 3479
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### List of products / product categories included in the scope of certificate

- **Stent systems**

– End of list –

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