

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.

MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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

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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