EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60106290 0001

Report No.: 21240046 001

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

Products: (see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60035711 0001

Expiry Date: 2020-12-07

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2015-12-08

Date: 2015-12-08

Notified Body

Dipl.-Ing. D. Meier

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.

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Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60106290 0001
Report No.: 21240046 001

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

Products:

- Syringes
- Needles
- Administration sets
- Blood collecting systems
- Angiographic-interventional catheter systems
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles
- Blood collecting systems

Date: 2015-12-08

Notified Body

Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle

Dipl.-Ing. D. Meier

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60106290 0001
Report No.: 21240046 001

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

Additional sites included:

TERUMO EUROPE N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Scope: Warehouse operations and distribution of medical devices

TERUMO UK
3 Unity Grove
Knowsley Business Park South, Knowsley,
Merseyside L34 9GT, United Kingdom

Scope: Design and development, manufacture of extracorporeal circuits for open heart surgery and ancillary circuits

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. D. Meier

Date: 2015-12-08