

**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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

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**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**



**Dipl.-Ing. D. Meier**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

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**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

**Date:** 2015-12-08

**Notified Body**

**Dipl.-Ing. D. Meier**

