

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

**Registration No.:** HD 60134707 0001

**Report No.:** 21240046 017

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

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

Replaces Certificate, Registration No.: HD 60106290 0001


**Expiry Date:** 2024-05-26

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:** 2020-04-21

**Date:** 2020-04-21

Notified Body

  
Dipl.-Ing. (FH) D. Wiedemuth



**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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3001 Leuven  
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**Products included:**

- Syringes
- Needles
- Administration sets
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Introducer for vascular access
- Angiographic Catheters
- Guidewire for Angiography

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

- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles

**Date:** 2020-04-21

**Notified Body**



*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**

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

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Belgium

additional sites included:

Terumo Europe N.V.  
European Distribution Center  
Brikkenovenstraat 48  
3600 Genk, Belgium

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

**Date:** 2020-04-21

Notified Body



*D. Wiedemuth*  
**Dipl.-Ing. (FH) D. Wiedemuth**