

# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization  
**TERUMO EUROPE N.V.**  
Interleuvenlaan 40  
3001 Leuven  
Belgium

has established and applies a quality management system for medical devices  
for the following scope:

**see attachment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-08  
Certificate Registration No.: SX 60134689 0001  
An audit was performed. Report No.: 21240046 013  
This Certificate is valid until: 2021-12-07

Certification Body



Date 2018-12-03



Dipl.-Ing. (FH) D. Wiedemuth

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

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

Doc. 1/7, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60134689 0001  
**Report No.:** 21240046 013

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

**Scope:**

Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Servicing of active medical devices.

**Certification Body**



**Date:** 2018-12-03



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

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

Doc. 2/7, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60134689 0001  
**Report No.:** 21240046 013

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

**Scope:** additional sites included:

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

Activities: Distribution of active and non-active medical  
devices, active implantable medical devices, and in-vitro  
diagnostic medical devices

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

Activities: Design and development, manufacture and  
sterilization of extra corporeal circuits for open heart  
surgery and ancillary devices

**Certification Body**



**Date:** 2018-12-03

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

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

Doc. 3/7, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60134689 0001  
**Report No.:** 21240046 013

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

**Scope:** additional sites included:

Marketing of active and non-active medical devices,  
active implantable medical devices, and in-vitro  
diagnostic medical devices:

Terumo Europe N.V.  
Terumo Interventional Systems - EMEA (TIS-EMEA)  
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Europe N.V., Terumo Cardiovascular Europe,  
Middle East & Africa (TCV-EMEA)  
Ludwig-Erhard-Straße 6, 65760 Eschborn, Germany

Terumo Europe N.V., Terumo Medical Products EMEA (TMP-EMEA)  
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Europe N.V., Diabetes Management EMEA (DM-EMEA)  
Interleuvenlaan 40, 3001 Leuven, Belgium

**Certification Body**



**Date:** 2018-12-03

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

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

Doc. 4/7, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60134689 0001  
**Report No.:** 21240046 013

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

**Scope:** additional sites included:

Distribution of active and non-active medical devices,  
active implantable medical devices, and in-vitro  
diagnostic medical devices:

Terumo Deutschland GmbH  
Ludwig-Erhard-Straße 6, 65760 Eschborn, Germany

Terumo Deutschland GmbH, Zweigniederlassung Switzerland  
Bodenackerstrasse 3, 8957 Spreitenbach, Switzerland

Terumo Deutschland GmbH, Zweigniederlassung Austria  
Liebermannstrasse F10-301, 2345 Brunn am Gebirge, Austria

Terumo Europe España SL  
Avda. Juan Carlos I, N°13-7 Planta, Edificio Torre La Garena  
28806 Alcalá de Henares (Madrid), Spain

**Certification Body**



**Date:** 2018-12-03

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

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

Doc. 5/7, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60134689 0001  
**Report No.:** 21240046 013

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

**Scope:** additional sites included:

Distribution of active and non-active medical devices,  
active implantable medical devices, and in-vitro  
diagnostic medical devices:

Terumo Europe N.V., Emerging Market Division  
Interleuvenlaan 40, 3001 Leuven, Belgium

Terumo Italia S.r.l.  
Via Paolo di Dono 73, 00142 Roma, Italy

Terumo France S.A.S.  
Bâtiment Renaissance, 3 rond-point des Saules,  
78280 Guyancourt, France

Terumo Sweden AB  
Sven Källfets gata 18,  
426 71 Västra Frölunda, Sweden

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**Date:** 2018-12-03

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

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

Doc. 6/7, Rev. 0

**Attachment to  
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**Registration No.:** SX 60134689 0001  
**Report No.:** 21240046 013

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

**Scope:** additional sites included:

Distribution of active and non-active medical devices,  
active implantable medical devices, and in-vitro  
diagnostic medical devices:

Terumo Europe UK Ltd.  
Otium House, 2 Freemantle Road, Bagshot Surrey GU19 5LL, UK

Terumo Poland Sp. Zoo  
Wisniowy Business Park budynek D, ul. 1 Sierpnia 6  
02-134 Warszawa, Poland

Terumo Europe N.V., Benelux Sales Division  
Interleuvenlaan 40, 3001 Leuven, Belgium

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**Date: 2018-12-03**

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

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

Doc. 7/7, Rev. 0

**Attachment to  
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**Registration No.:** SX 60134689 0001  
**Report No.:** 21240046 013

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

**Scope:** additional sites included:

Marketing and distribution of active and non-active  
medical devices:

Terumo Europe N.V., Terumo Pharmaceutical Solutions  
Interleuvenlaan 40, 3001 Leuven, Belgium

**Certification Body**



**Date:** 2018-12-03

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