

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



[Signature]
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
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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 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

Certification Body



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
Certificate**

Registration No.: SX 60134689 0001
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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
Certificate**

Registration No.: SX 60134689 0001
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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