TÜVRheinland®

# 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 |

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certification Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

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

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Doc. 1/7, Rev. 0

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

**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**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland

**Date:** 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

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Doc. 2/7, Rev. 0

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

**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**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

**Date:** 2018-12-03

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

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

**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**

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Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

**Date:** 2018-12-03

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth

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

**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 diagnotic medical devices:

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

Terumo Deutschland GmbH, Zweigniederlassung Switzerland
Bodenäckerstrasse 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

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Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

**Certification Body**

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

**Date:** 2018-12-03

Dipl.-Ing. (FH) D. Wiedemuth

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

**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 diagnotic 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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Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

**Certification Body**

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

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

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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 diagnotic 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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# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

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**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

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Deutsche Akkreditierungsstelle
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