

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1594584-1

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

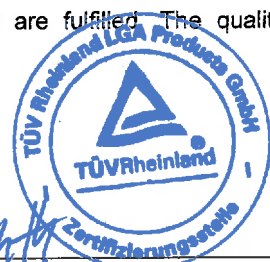
Scope: Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

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

Installation and serving of active medical devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25



D. Wiedemuth
Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TERUMO EUROPE N.V. Interleuvenlaan 40 3001 Leuven Belgium	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. Installation and serving of active medical devices
/02	c/o Terumo Europe UK 3 Unity Grove Knowsley Business Park South Merseyside, Knowsley L34 9GT United Kingdom	Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

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The scope of certification also covers the following sites:

- | | | |
|-----|--|--|
| /03 | c/o Terumo Deutschland GmbH
Ludwig-Erhard-Str. 6
65760 Eschborn
Germany | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /04 | c/o Terumo France S.A.S.
Bâtiment Renaissance, 3 rond-point des Saules
Guyancourt
France 78280 | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /05 | c/o Terumo Italia S.r.l.
Via Paolo di Dono 73
00142 Roma
Italy | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /06 | c/o Terumo Europe España SL
Avda. Juan Carlos I, N°13-7 Planta
28806 Alcalá de Henares (Madrid)
Spain | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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- | | | |
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| /07 | c/o Terumo Europe UK Ltd.
Otium House
2 Freemantle Road
Bagshot
Surrey
GU19 5LL
United Kingdom | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /08 | c/o Terumo Europe N.V.
Benelux Sales Division
Interleuvenlaan 40
3001 Leuven
Belgium | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /09 | c/o Terumo Sweden AB
Sven Källfets gata 16
SE-426 71 Västra Frölunda
Sweden | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /10 | c/o Terumo Deutschland GmbH
Zweigniederlassung Switzerland
Bodenackerstrasse 3
8957 Spreitenbach
Switzerland | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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- | | | |
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| /11 | c/o Terumo Europe N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk
Belgium | Storage and distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /12 | c/o Terumo Europe N.V.
Terumo Interventional Systems
EMEA (TIS-EMEA)
Interleuvenlaan 40
3001 Leuven
Belgium | Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /13 | c/o Terumo Europe N.V.
Terumo Cardiovascular Europe
Middle East & Africa (TCV-EMEA)
Ludwig-Erhard-Straße 6
65760 Eschborn
Germany | Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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- | | | |
|-----|--|--|
| /14 | c/o Terumo Europe N.V.
Terumo Medical Products
EMEA (TMP-EMEA)
Interleuvenlaan 40
3001 Leuven
Belgium | Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /15 | c/o Terumo Europe N.V.
Diabetes Management
EMEA (DM-EMEA)
Interleuvenlaan 40
3001 Leuven
Belgium | Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /16 | c/o Terumo Europe N.V.
Terumo Pharmaceutical Solutions
Interleuvenlaan 40
3001 Leuven
Belgium | Marketing of active and non-active medical devices and active implantable medical devices |
| /17 | c/o Terumo Deutschland GmbH
Zweigniederlassung Austria
Liebermannstrasse F10-301
2345 Brunn am Gebirge
Austria | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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- | | | |
|-----|--|--|
| /18 | c/o Terumo Europe N.V.
Emerging Market Division
Interleuvenlaan 40
3001 Leuven
Belgium | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |
| /19 | c/o Terumo Poland Sp. Zoo
Wisniowy Business Park budynek D
ul. 1 Sierpnia 6
02-134 Warszawa
Poland | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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