

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

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

**Design and development, manufacture and distribution
of active, non-active medical devices and IVD
medical devices and servicing of active medical devices
(see attachments for products and sites included)**

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: 2018-12-28
Certificate Registration No.: SX 60135471 0001
An audit was performed. Report No.: 12031336 004
This Certificate is valid until: 2020-08-29

Certification Body



Date 2018-12-28




Masahiro Asami

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. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60135471 0001
Report No.: 12031336 004

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Scope:

Products included:

- Solution Administration Sets
- Needles
- Syringes
- IV Catheters
- Blood Collection Systems
- Sterile Tube Connecting Systems
- Blood Glucose Monitoring Systems
- Stents
- Catheter and Guide Wire Systems
- Oxygenator Systems
- Extension Tube
- Blood Transfusion Systems
- Apheresis Systems
- Filter Systems
- Infusion Pumps
- Syringe Infusion Pumps

Certification Body



Date: 2018-12-28


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60135471 0001
Report No.: 12031336 004

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Scope:

Products included:

- Clinical Electronic Blood-Pressure Monitors
- Clinical Electronic Thermometer
- Medical Equipments for Blood Collection
- Medical Equipments for APD Systems
- Vascular Grafts
- Coronary Optical Coherence Tomography Systems
- Prefillable Syringes

Site included:

Terumo Corporation - Tokyo Office
3-20-2, Nishi-Shinjuku, Shinjuku-ku, Tokyo, 163-1450 Japan

Scope:

Activities related to corporate management processes

Certification Body



Date: 2018-12-28



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60135471 0001
Report No.: 12031336 004

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Scope:

Site included:

Terumo Corporation - Shonan Center
1500, Inokuchi, Nakai-machi, Ashigarakami-gun, Kanagawa,
259-0151, Japan

Scope:

Activities related to customer communication processes and
distribution of active, non-active and IVD medical devices

Certification Body



Date: 2018-12-28


Masahiro Asami