

# 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**

**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**

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**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**



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**Attachment to  
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**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**