

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1485480-1

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

Scope: Design and Development, Manufacture, Distribution and Service of

- 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
- Clinical Electronic Blood-Pressure Monitors

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.: 12031336 025

Effective date: 2020-10-23

Expiry date: 2021-08-29

Issue date: 2020-10-23



M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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- Clinical Electronic Thermometer
- Medical Equipments for Blood Collection
- Medical Equipments for APD Systems
- Vascular Grafts
- Coronary Optical Coherence Tomography Systems
- Prefillable Syringes
- Portable insulin infusion pump
- Portable insulin infusion administration set

TÜVRheinland

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M. Aihara

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| No. | Facility | Scope |
|-----|---|---|
| /02 | Terumo Corporation - Tokyo office 3-20-2 Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan | Activities related to corporate management processes |
| /03 | Terumo Corporation, Shonan Center 1500 Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan | Activities related to customer communication processes and distribution of active, non-active and IVD medical devices |

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