Certificate

Quality Management System
EN ISO 13485:2016 + AC:2018 + A11:2021
ISO 13485:2016

Registration No.:	SX 1485480-1
Certificate Holder:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
Scope:	Design and Development, Manufacture, Distribution and Service of - Angiographic Catheter and Accessories - Anti-adhesion System - Balloon Dilatation Catheter - Blood Collection/Transfusion Device and Accessories - Blood Glucose Monitoring system - Cartridge Injection System - Catheter Introducer and Accessories - Electronic Sphygmomanometer - Electronic Thermometer - Embolization Prosthesis and Accessories - Extracorporeal Circulation Device and Accessories - Falloposcopic Tuboplasty Device and Accessories - Guide Wire and Accessories - Guiding/Micro Catheter and Accessories - Infusion Pump - Infusion Set and Accessories - Intravascular Imaging Catheter and Accessories - Intravascular Imaging System and Accessories - Intravenous Catheter

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.:	150320378-301
Effective date:	2026-08-30
Expiry date:	2029-08-29
Issue date:	2026-06-01

Replaces certificate SX 1485480-1 issued 2025-07-07

This certificate can be validated on https://www.certipedia.com

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

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

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Precisely Right.

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44-1, 2-chome, Hatagaya,
Shibuya-ku, Tokyo
151-0072, Japan

- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo Office 2-6-1 Toranomon, Minato-ku, Tokyo 105-5528, Japan	Aspects related to Design and Development, Manufacture, Service and activities related to corporate management processes.
/03	c/o Terumo Corporation - Shonan Center 1500 Inokuchi, Nakai-machi, Ashigarakami-gun, Kanagawa 259-0151, Japan	Aspects related to Distribution and activities related to customer communication processes.

This certificate can be validated on https://www.certipedia.com

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