

Terufusion™

Infusion System

Infusion Sets



TERUMO

Terufusion™

A clear view on infusion

with a comprehensive portfolio of solutions.

Terumo Infusion Sets



Easy handling

- Easy setting following the instruction screen of the pump
- Sharp 2-way spike to penetrate bags and bottles easily
- Adjustable roller clamp with notch to mount tubing during priming

Increased patient safety

- AFF clip for prevention of accidental bolus infusion
- Does not contain DEHP
- Y-site with NLCD* for prevention of needle stick injuries[†]

Highly accurate infusion

- Reliable high accuracy combination of Terufusion™ pump & sets[‡]
- Durable tubes for continuous accurate infusion[§]

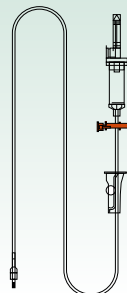
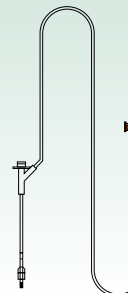
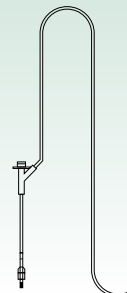
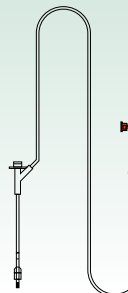
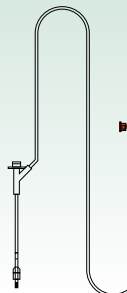
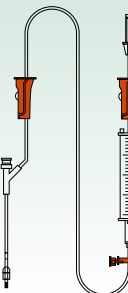
* Needleless connecting device

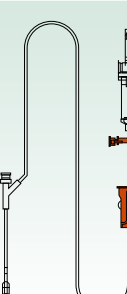
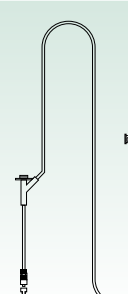
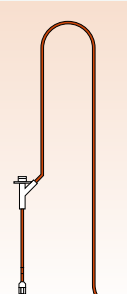
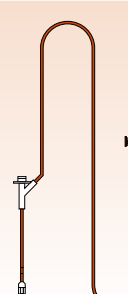
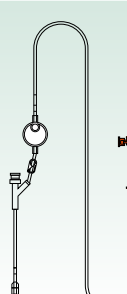
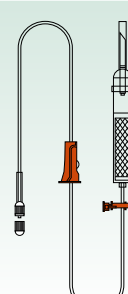
[†] Available on specific sets

[‡] Flow rate accuracy: within $\pm 5\%$

[§] Always consult the product label and IFU for a complete overview of warnings, cautions and/or precautions prior to actual use.

Portfolio

Type	General					
Product code	TI*PU300WY	TI*PJ300WY01	YI*PU400WN01	YI*PU400WY51	YI*PU400WY21	TI*PM370WYE ¹
AFF clip	Yes	Yes	No	Yes	Yes	Yes
Filter (um)	15	15	15	15	15	15
Pump tube (mm)	2000	2000	2000	2500	2200	2200
Injector port	None	Needle port	Needle port	Needle port	Needle port	NLCD ²
Drip rate (drops/ml)	20	20	20	20	20	20
Material - tubing	PVC ³	Polybutadiene ⁴	PVC ³	PVC ³	PVC ³	PVC ³
Packaging (unit/carton)	20/200	20/200	20/200	20/200	20/200	10/100
Priming volume (ml) ⁵	15.7	16.7	17.5	21.4	19.1	19.4
Colour ⁶	Transparent	Transparent	Transparent	Transparent	Transparent	Transparent
Pressure resistance (bar)	1.5	1.5	1.5	1.5	1.5	1.5
Total length of sets	2150	2440	2270	2770	2470	2985
						

Type	General		General (amber)		Oncology	Transfusion
Product code	SP*PT306WY01E	PT+PU400WY	TI*PA300WN01E	TI*PA300WY01E	SP*PF306WY01E	TB*PU300SYE
AFF clip	Yes	Yes	No	Yes	Yes	Yes
Filter (um)	15	15	15	15	0.2	200
Pump tube (mm)	2200	2000	2000	2000	2200	2200
Injector port	NLCD ²	Needle port	Needle port	Needle port	NLCD ²	None
Drip rate (drops/ml)	20	20	20	20	20	20
Material - tubing	Polybutadiene ⁴	PVC ³	PVC ³	PVC ³	Polybutadiene ⁴	PVC ³
Packaging (unit/carton)	20/200	25/250	20/200	20/200	20/200	20/200
Priming volume (ml) ⁵	18.2	18.1	18.2	18.2	18.4	17.2
Colour ⁶	Transparent	Transparent	Amber	Amber	Transparent	Transparent
Pressure resistance (bar)	1.5	1.5	1.5	1.5	1.5	1.5
Total length of sets	2640	2380	2640	2640	2860	2420
						

Terufusion™



Full focus infusion system.



Terumo offers a comprehensive portfolio of solutions for the complete infusion line-up

User-friendly syringe and volumetric pumps and racks, as well as a wide range of highly accurate, easy-to-use disposables, such as an extended range of infusion sets and syringes.



Terumo Corporation
+81 3 6742 8500

Terumo Europe N.V.
+32 16 38 12 11

Your Terumo partner



www.terumo-europe.com



All brand names are trademarks or registered trademarks of TERUMO CORPORATION and their respective owners.
Published by Terumo Europe N.V.

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145252 0001

Report No.: 12031336 018

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

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-23

Date: 2019-12-23



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**


Registration No.: HD 60145252 0001
Report No.: 12031336 023

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

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Notified Body


M.Sc. M. Aihara



Date: 2020-10-23

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60145252 0001
Report No.: 12031336 023

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

Products included:

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Portable insulin infusion pump
- Portable insulin infusion administration set

Notified Body



Date: 2020-10-23

M. Aihara
M.Sc. M. Aihara

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

- 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
- Endoscopic Vessel Harvesting System
- 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

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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Maihara

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

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

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- 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 Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



Michihara

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

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

The scope of certification also covers the following:

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 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development 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.

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29



M. Aihara

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

