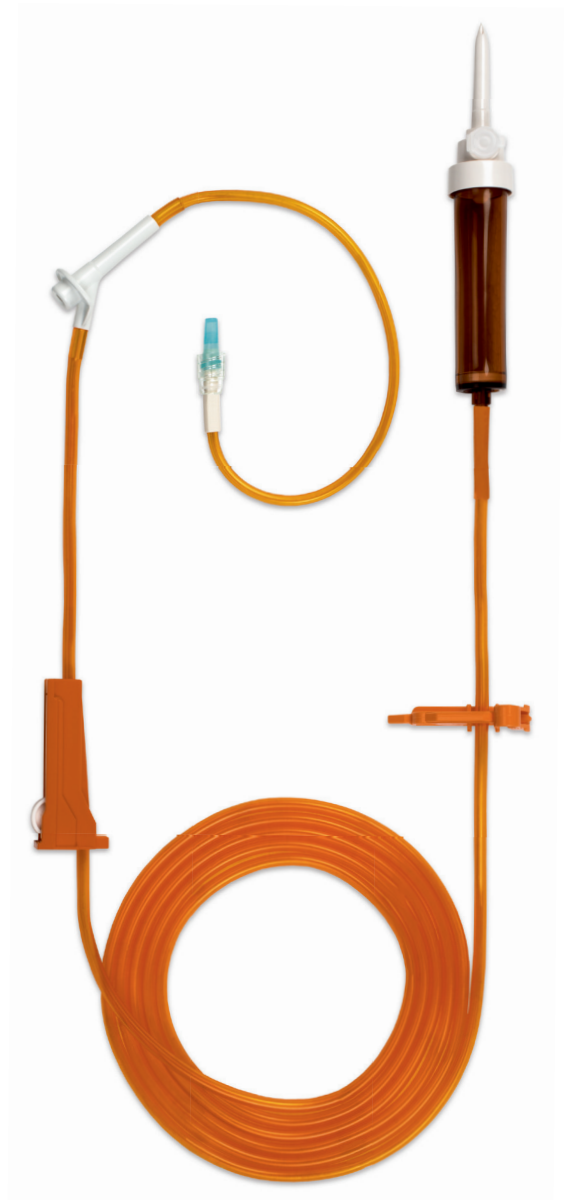
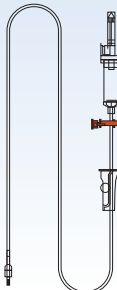
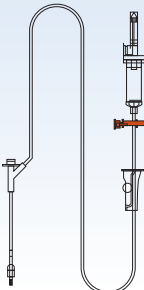
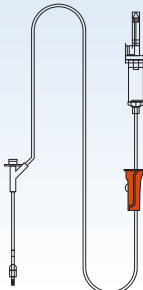
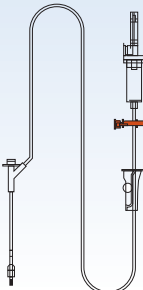
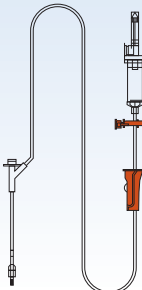
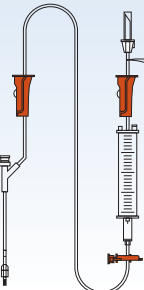
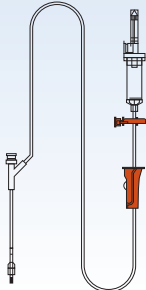
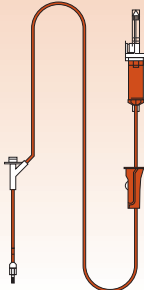
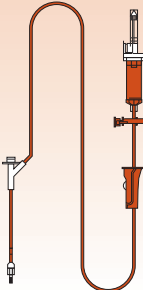
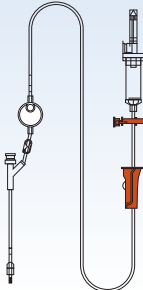
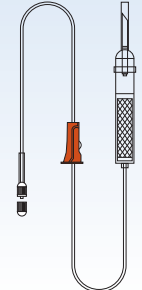
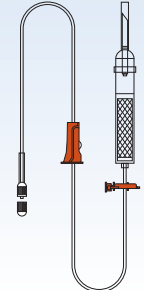


Infusion and Extension Sets

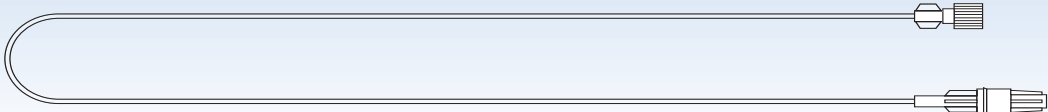


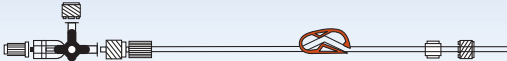
Infusion Sets

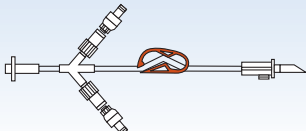
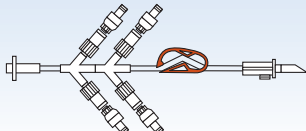
Type	General					
Product code	TI*PU300WY	TI*PJ300WY01	YI*PU400WN01	YI*PU400WY51	YI*PU400WY21	TI*PM370WYE ¹
AFF clip	Yes	Yes	No	Yes	Yes	Yes
Filter (um)	15	15	15	15	15	15
Pump tube (mm)	2000	2000	2000	2500	2200	2200
Injector port	None	Needle port	Needle port	Needle port	Needle port	NLCD ²
Drip rate (drops/ml)	20	20	20	20	20	60
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	20/200
Priming volume (ml)	15,7	16,8	16,9	20,7	18,1	19,4
Colour ⁵	Transparent	Transparent	Transparent	Transparent	Transparent	Transparent
Pressure resistance (bar)	2	2	2	2	2	2
Total length of sets	2150	2440	2270	2770	2470	2985
						

Type	General	General (amber)		Oncology	Transfusion	
Product code	SP*PT306WY01E	TI*PA300WN01E	TI*PA300WY01E	SP*PF306WY01E	TB*PU300SE	TB*PU300SYE
AFF clip	Yes	No	Yes	Yes	No	Yes
Filter (um)	15	15	15	0,2	200	200
Tube length (mm)	2200	2000	2000	2200	2200	2200
Injector port	NLCD ²	Needle port	Needle port	NLCD ²	None	None
Drip rate (drops/ml)	20	20	20	20	20	20
Material - tubing	Polybutadiene ⁴	PVC ³	PVC ³	Polybutadiene ⁴	PVC ³	PVC ³
Packaging (unit/carton)	20/200	20/200	20/200	20/200	20/200	20/200
Priming volume (ml)	18,3	17,4	17,4	20,2	17,4	17,4
Colour ⁵	Transparent	Amber	Amber	Transparent	Transparent	Transparent
Pressure resistance (bar)	2	2	2	2	2	2
Total length of sets	2640	2640	2640	2860	2420	2420
						

Extension Sets

Type	Basic					
Product code	EX+300TN1FL	EX+200TN1FL	EX+150TN1FL	EX+075TN1FL	EX+050TN1FL	EX+025TN1FL
Material - tubing	PVC ¹	PVC ¹	PVC ¹	PVC ¹	PVC ¹	PVC ¹
Colour - tubing	Transparent	Transparent	Transparent	Transparent	Transparent	Transparent
Tube length (cm)	300	200	150	75	50	25
Connection 1	FFLL ²	FFLL ²	FFLL ²	FFLL ²	FFLL ²	FFLL ²
Connection 2	FMLL ³	FMLL ³	FMLL ³	FMLL ³	FMLL ³	FMLL ³
Clip	No	No	No	No	No	No
Priming volume (ml)	5,3	3,5	2,6	1,5	1	0,5
Pressure resistance (bar)	4	4	4	4	4	4
						

Type	Amber				3-way tap			
Product code	EX+250AN1FL	EX+200AN1FL	EX+150AN1FL	EX+025AN1FL	EX+200TNTAP	EX+150TNTAP	EX+050TNTAP	EX+025TNTAP
Material - tubing	PUR ⁴	PUR ⁴	PUR ⁴	PUR ⁴	PVC ¹	PVC ¹	PVC ¹	PVC ¹
Colour - tubing	Amber	Amber	Amber	Amber	Transparent	Transparent	Transparent	Transparent
Tube length (cm)	250	200	150	25	200	150	50	25
Connection 1	FFLL ²	FFLL ²	FFLL ²	FFLL ²	3-way tap	3-way tap	3-way tap	3-way tap
Connection 2	RMLL ⁵	RMLL ⁵	RMLL ⁵	RMLL ⁵	FMLL ³	FMLL ³	FMLL ³	FMLL ³
Clip	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Priming volume (ml)	2,0	1,6	1,2	0,5	2,2	2,0	1,0	0,5
Pressure resistance (bar)	21	21	21	21	4	4	4	4
								

Type	Add-on	
Product code	AO+T2NFD	AO+T4NFD
Material - tubing	PVC ¹	PVC ¹
Colour - tubing	Transparent	Transparent
Tube length (cm)	25+3	25+3
Connection 1	2 x (NLCD ⁶ +BCV ⁷)	4 x (NLCD ⁶ +BCV ⁷)
Connection 2	Piercing connector	Piercing connector
Clip	Yes	Yes
Priming volume (ml)	2,0	2,4
Pressure resistance (bar)	2	2
		

1 Does not contain DEHP · 2 FFLL = Fixed Female Luer Lock · 3 FMLL = Fixed Male Luer Lock · 4 Does not contain PVC · 5 RMLL = Rotating Male Luer Lock · 6 Needleless connecting device · 7 BCV = Back Check Valve



Terumo Infusion Sets

Easy handling

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

Increased patient safety

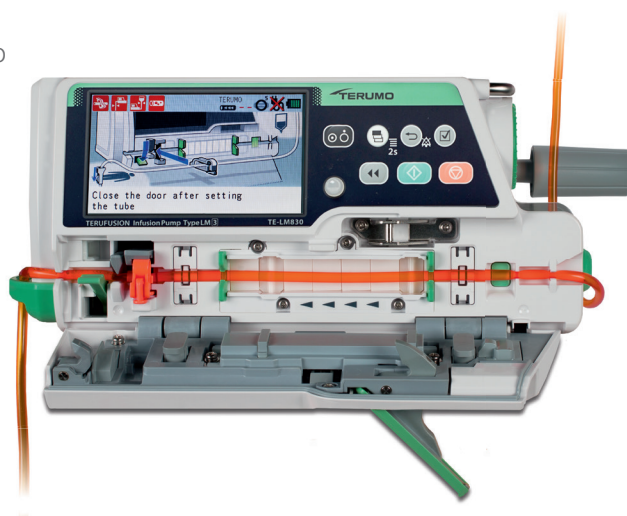
- AFF clip for prevention of accidental bolus infusion
- Does not contain DEHP
- Y-site with NLCD* for prevention of needle stick injuries

Highly accurate infusion

- Reliable high accuracy combination of Terumo pump & sets**
- Durable tubes for continuous accurate infusion

* Needleless connecting device

** Flow rate accuracy: within $\pm 5\%$



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 3374 8111

Terumo Europe NV
+32 16 38 12 11

Your Terumo partner

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

Registration No.: HD 60121893 0001

Report No.: 12031336 001

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 60077473 0001

Expiry Date: 2022-08-29

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: 2017-08-30

Date: 2017-08-25



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

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60121893 0001
Report No.: 12031336 001

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

Date: 2017-08-25



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60121893 0001
Report No.: 12031336 001

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

Date: 2017-08-25



Notified Body

M. Aihara
M.Sc. M. Aihara



DECLARATION OF CONFORMITY

Manufacturer: Terumo Medical Products(Hangzhou) Co.,Ltd,
M4-9-5 Hangzhou Economic & Technological Development Zone,
310018 Hangzhou, People's Republic of China

European Representative: TERUMO EUROPE N.V.
Interleuvenlaan 40,3001 Leuven, Belgium

Product Name: Solution Administration Set for Infusion Pump

Model Number: See attachment

UMDNS Code: 16579+17984

Classification (MDD, Annex IX): II a,rule 2

Conformity Assessment Route: Annex II, excluding 4

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Standard Applied: All applicable harmonized standard

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Identification number: CE0123

(EC) Certificate: G1 16 06 37584 019

Expire date of the Certificate: 2021-09-10

Start of CE Marking: February 08,2010

Place, Date of Issue: Hangzhou, 2016-08-29

Signature: Tsuneo Nakada

Name: Nakada Tsuneo

Position: General Manager

ATTACHMENT:

Common Name: Solution Administration Set for Infusion Pump	
Brand Name	Model number
TERUFUSION Solution Administration Set for Infusion Pump	TI*PU300WN01
	TI*PU300WN01E
	TI*PU200WN01
	TI*PU300W
	TI*PU200W
	TI*PJ300WN01
	TI*PU200WY01
	TI*PU300WY
	TI*PU200WY
	TI*PJ300WY01
	TI*PU300WY01
	TI*PU300WY01E
	TI*PU300WY11E
	YI*PU400WN01
	YI*PU400WY01
	YI*PU400WY21
	YI*PU400WY51
	YI*PU400WN00
	YI*PU400WY00
	YI*PU400WY20
	YI*PU400WY50
	YI*PU300WN01
	YI*PU300WY01
	YI*PU300WY21
	YI*PU300WY51
	YI*PU300WN00
	YI*PU300WY00
	YI*PU300WY20
	YI*PU300WY50
	YI*PU200WN01
	YI*PU200WY01
	YI*PU200WN00
	YI*PU200WY00
	TI*PU300WN31
	TI*PU300WY31
	TI*PU300WN30
	TI*PU300WY30

SURPLUG Solution Administration Set	SP*PF306WY01
	SP*PF306W01
	SP*PF306WY01E
	SP*PT306WY01E
TERUFUSION Solution Administration Set for infusion pump (Burette)	TI*PM370W
	TI*PM370WY
	TI*PM370WYE
TERUFUSION Solution Administration Set for infusion pump (for Photosensitive drugs)	TI*PA300WN01
	TI*PA300WN01E
	TI*PA300WY01
	TI*PA300WY01E
Chemoshield Infusion Set	KS*PT30L1AN
	KS*PT30L1AY
	KS*PF30L1AN
	KS*PF30L1AY

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



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



Michiaki Aihara
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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



Michiaki Aihara

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