Terufusion™

Infusion System

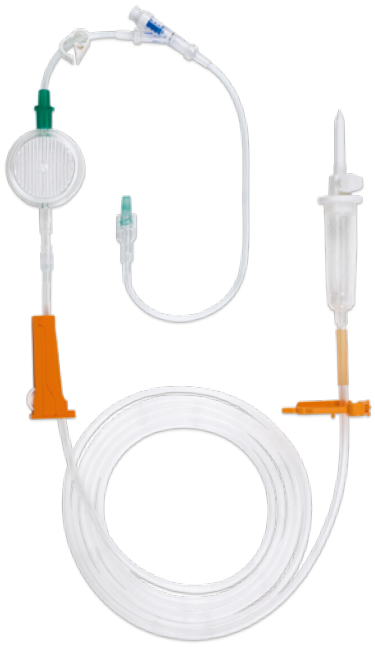
Infusion Sets

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

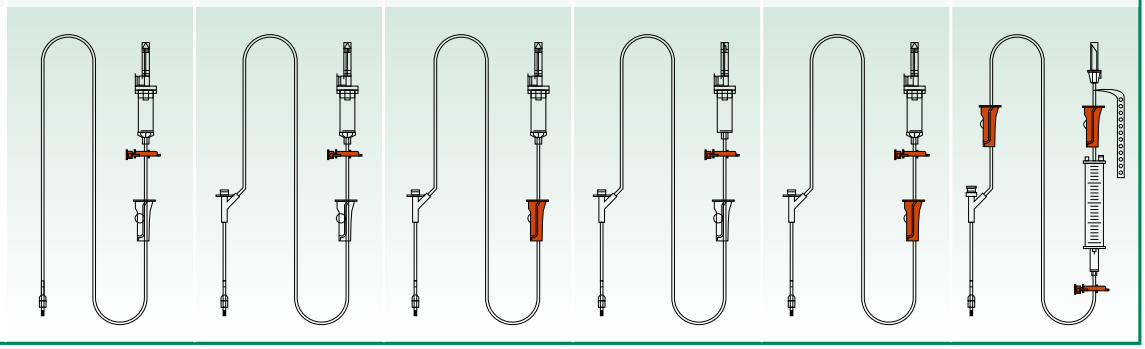
- AFF clip for prevention of accidental bolus infusion
- Does not contain DEHP
- Y-site with NLCD* for prevention of needle stick injuries+

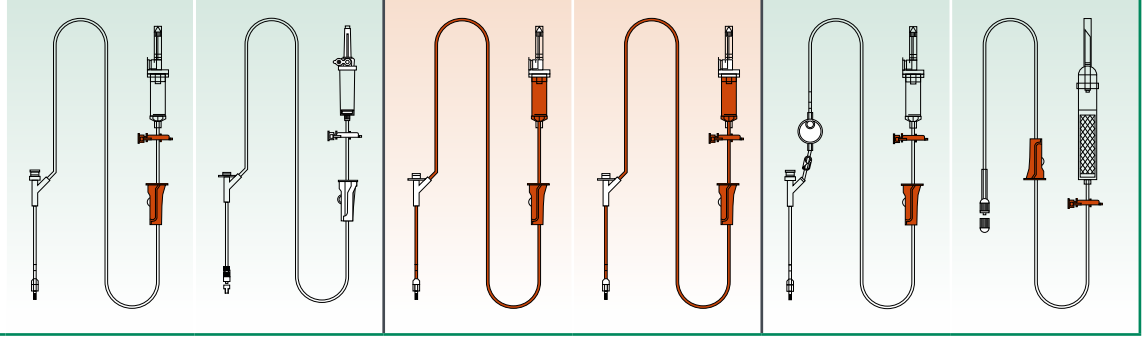
Highly accurate infusion

- 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 ± 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
						

1 with Burette 150ml · 2 Needleless connecting device · 3 Does not contain DEHP · 4 Does not contain PVC · 5 Total volume of the infusion line (drip chamber empty) · 6 Tubing & Drip chamber

Terufusion™

EASY HANDLING
ENHANCED SAFETY
Terufusion™
OPTIMIZED WORKFLOW

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

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

Your Terumo partner

www.terumo-europe.com

MP2516B-0122FK-I(04.2022)E

Poly Medicure Limited
Plot No.104-105, Sector-59, HSIIDC Industrial Area,
Ballabgarh, Faridabad - 121004, Haryana (INDIA)
T: +91-129-3355070, 4287000, F: +91-129-2307007, 2309102
E: info@polymedicure.com W: polymedicure.com

POLYMED MEDICAL DEVICES
We Care As We Cure

6th October 2022

EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabhgarh - 121004, Faridabad, INDIA.

Hereby declare and take responsibility to ensure that the following product:

S. No.	Product Description	Product Code	Terumo Ref. Code
01	Infusion Sets	14370	PT+PU400WY

As per Annexure – IX of the Medical Device Directive comply with the product standards/ requirements and, meet the essential requirements according to Annexure- I of the Council Directive 93/42/EEC of 14th June 1993 as amended by 2007/47/EC concerning medical devices.

Conformity Assessment Procedure was carried out according to Annexure - II excluding section 4 of the MDD and is certified by the following Notified Body.

Name, Address & No. : TÜV SÜD Product Service GmbH,
Ridlerstraße 65, 80339, Munich, Germany
Notified Body Number 0123,

CE Certificate No. : G1 041938 0007

European Authorized Representative Address : OBELIS S.A.
Boulevard Général Wahis 53,
B-1030, Brussels, Belgium,
mail@obelis.net

R D Sharma
GM – CQRA & PRRC
On behalf of POLY MEDICURE LTD. Faridabad

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.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.

TÜVRheinland®

Doc. 1/2, Rev.1

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.1

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-10-23

M.Sc. M. Aihara

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Installation and serving of active medical devices.

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.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TERUMO EUROPE N.V. Interleuvenlaan 40 3001 Leuven Belgium	Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories. Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices. Installation and serving of active medical devices
/02	c/o Terumo Europe UK 3 Unity Grove Knowsley Business Park South Merseyside, Knowsley L34 9GT United Kingdom	Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

Report No.: 3350367-50
Effective date: 2021-12-08
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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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Registration No.: SX 1594584-1

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/03	c/o Terumo Deutschland GmbH Ludwig-Erhard-Str. 6 65760 Eschborn Germany	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/04	c/o Terumo France S.A.S. Bâtiment Renaissance, 3 rond-point des Saules 78280 Guyancourt France	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/05	c/o Terumo Italia S.r.l. Via Paolo di Dono 73 00142 Roma Italy	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/06	c/o Terumo Europe España SL Avda. Juan Carlos I, N°13-7 Planta 28806 Alcalá de Henares (Madrid) Spain	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/07	c/o Terumo Europe UK Ltd. Otium House 2 Freemantle Road Bagshot Surrey GU19 5LL United Kingdom	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/08	c/o Terumo Europe N.V. Benelux Sales Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/09	c/o Terumo Sweden AB Sven Källfets gata 16 SE-426 71 Västra Frölunda Sweden	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/10	c/o Terumo Deutschland GmbH Zweigniederlassung Switzerland Bodenäckerstrasse 3 8957 Spreitenbach Switzerland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/11	c/o Terumo Europe N.V. European Distribution Center Brikkenovenstraat 48 3600 Genk Belgium	Storage and distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/12	c/o Terumo Europe N.V. Terumo Interventional Systems EMEA (TIS-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/13	c/o Terumo Europe N.V. Terumo Cardiovascular Europe Middle East & Africa (TCV-EMEA) Ludwig-Erhard-Straße 6 65760 Eschborn Germany	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/14	c/o Terumo Europe N.V. Terumo Medical Products EMEA (TMP-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/15	c/o Terumo Europe N.V. Diabetes Management EMEA (DM-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/16	c/o Terumo Europe N.V. Terumo Pharmaceutical Solutions Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices and active implantable medical devices
/17	c/o Terumo Deutschland GmbH Zweigniederlassung Austria Liebermannstrasse F10-301 2345 Brunn am Gebirge Austria	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/18	c/o Terumo Europe N.V. Emerging Market Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/19	c/o Terumo Poland Sp. Zoo Wisniowy Business Park budynek D ul. 1 Sierpnia 6 02-134 Warszawa Poland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

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