

# 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<sup>†</sup>

#### Highly accurate infusion

- Reliable high accuracy combination of Terufusion™ pump & sets<sup>‡</sup>
- Durable tubes for continuous accurate infusion<sup>§</sup>

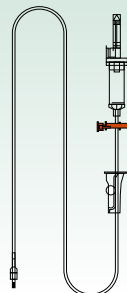
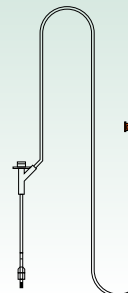
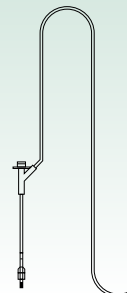
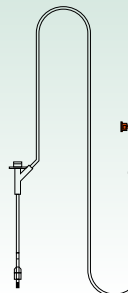
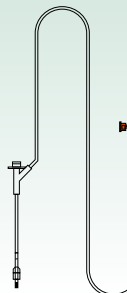
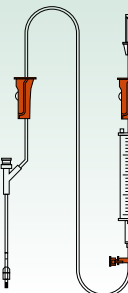
\* Needleless connecting device

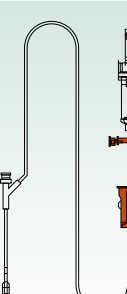
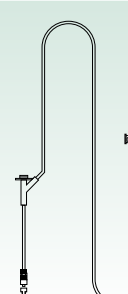
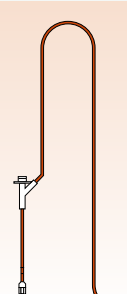
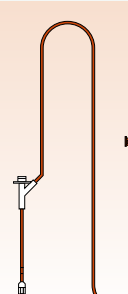
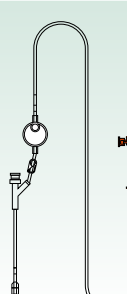
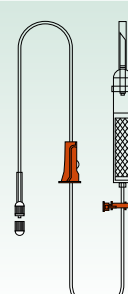
<sup>†</sup> Available on specific sets

<sup>‡</sup> Flow rate accuracy: within  $\pm 5\%$

<sup>§</sup> 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 <sup>1</sup>
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 <sup>2</sup>
Drip rate (drops/ml)	20	20	20	20	20	20
Material - tubing	PVC <sup>3</sup>	Polybutadiene <sup>4</sup>	PVC <sup>3</sup>	PVC <sup>3</sup>	PVC <sup>3</sup>	PVC <sup>3</sup>
Packaging (unit/carton)	20/200	20/200	20/200	20/200	20/200	10/100
Priming volume (ml) <sup>5</sup>	15.7	16.7	17.5	21.4	19.1	19.4
Colour <sup>6</sup>	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 <sup>2</sup>	Needle port	Needle port	Needle port	NLCD <sup>2</sup>	None
Drip rate (drops/ml)	20	20	20	20	20	20
Material - tubing	Polybutadiene <sup>4</sup>	PVC <sup>3</sup>	PVC <sup>3</sup>	PVC <sup>3</sup>	Polybutadiene <sup>4</sup>	PVC <sup>3</sup>
Packaging (unit/carton)	20/200	25/250	20/200	20/200	20/200	20/200
Priming volume (ml) <sup>5</sup>	18.2	18.1	18.2	18.2	18.4	17.2
Colour <sup>6</sup>	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](http://www.terumo-europe.com)



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Published by Terumo Europe N.V.

## Poly Medicure Limited

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T: +91-129-3355070, 4287000, F: +91-129-2307007, 2309102  
E: info@polymedicure.com W: polymedicure.com



6<sup>th</sup> October 2022

### EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabgarh - 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 14<sup>th</sup> 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. 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 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



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

# Certificate



## 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  
Expiry date: 2024-12-07  
Issue date: 2021-11-25



Dipl.-Ing. (FH) D. Wiedemuth  
TÜV Rheinland LGA Products GmbH  
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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<br>Ludwig-Erhard-Str. 6<br>65760 Eschborn<br>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.<br>Bâtiment Renaissance, 3 rond-point des Saules<br>Guyancourt<br>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.<br>Via Paolo di Dono 73<br>00142 Roma<br>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<br>Avda. Juan Carlos I, N°13-7 Planta<br>28806 Alcalá de Henares (Madrid)<br>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.<br>Otium House<br>2 Freemantle Road<br>Bagshot<br>Surrey<br>GU19 5LL<br>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.<br>Benelux Sales Division<br>Interleuvenlaan 40<br>3001 Leuven<br>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<br>Sven Källfets gata 16<br>SE-426 71 Västra Frölunda<br>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<br>Zweigniederlassung Switzerland<br>Bodenackerstrasse 3<br>8957 Spreitenbach<br>Switzerland | Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices |

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Interleuvenlaan 40  
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Belgium

The scope of certification also covers the following sites:

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

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3001 Leuven  
Belgium

The scope of certification also covers the following sites:

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

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Belgium

The scope of certification also covers the following sites:

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

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