Smart Infusion System

TERUFUSION® Infusion Pump Type LM Series
Syringe Pump Type SS Series

Specifications

Product name	TERUFUSION Communication Rack System	TERUFUSION Standard Rack System
Model	TE-RS800	TE-RS700
Functions	• Power output: Supplies AC power source to the attached pumps. • Communication method selection/display: Enables users to select a method of communicating with an external device, and displays the communication method. • Signal intensity indication: Indicates the signal intensity of the wireless LAN. • Pump status recording/transmission: Periodically monitors and records the statuses of the pump, and transmits them to an external device. • Command pass-through: Enables communication between an external device and a pump via this product.	Power output: Supplies AC power source to the attached pumps.
Communication function	Infrared communication is available with a pump having the infrared communication function(Max. 9 channels). Serial communication with an external device is available. Communication with an external device is available via wired LAN. Communication with an external device is available via wireless LAN.	
Operating conditions	5 to 40, relative humidity 20 to 90%RH (no condensation)	5 to 40, relative humidity 20 to 90%RH (no condensation)
Storage conditions	-20 to 45, relative humidity 10 to 95%RH (no condensation)	-20 to 45, relative humidity 10 to 95%RH (no condensation)
Power source	AC 100-240V, 50-60Hz Internal battery (Ni-MH battery) The power supplied by the internal battery is for the operation of this product, not for the attached pumps. • Continuous hours of use: approx. 5 hours (With the ambient temperature of 25°C, a new battery, fully charged, nine pumps attached and no connection for external communication) • Charging time: 15 hours or more (When charged from AC power source with the power off)	AC 100-240 V, 50-60 Hz
Rated output/Rated frequency	AC 100-240V, 50-60Hz (Up to nine pumps can be supplied with power*)	AC 100-240 V, 50-60 Hz (Up to nine pumps can be supplied with power*)
Power consumption	Communication Rack System x1: Max.152VA (When three pumps are attached*) Communication Rack System x1 + Communication Rack System (extension) x1: Max.236VA (When six pumps are attached*) Communication Rack System x1 + Communication Rack System (extension) x2: Max.320VA (When nine pumps are attached*)	Standard Rack System x1: Max.102VA (When three pumps are attached*) Standard Rack System x2: Max.204VA (When six pumps are attached*) Standard Rack System x3: Max.306VA (When nine pumps are attached*)
Classification	Class I equipment and internally powered equipment, continuous operation, IP22	Class I equipment, continuous operation, IP22
Dimensions	Communication Rack System x1: 220 mm (W) x 559 mm (H) x 199 mm (D) (Approx.) Communication Rack System x1 + Communication Rack System (extension) x1: 220 mm (W) x 946 mm (H) x 199 mm (D) (Approx.) Communication Rack System x1 + Communication Rack System (extension) x2: 220 mm (W) x 1333 mm (H) x 199 mm (D) (Approx.)	Standard Rack System x1: 220 mm (W) x 458 mm(H) x 132 mm(D) (Approx.) Standard Rack System x2: 220 mm (W) x 845 mm(H) x 132 mm(D) (Approx.) Standard Rack System x3: 220 mm (W) x 1232 mm(H) x 132 mm(D) (Approx.)
Weight	Communication Rack System x1: Approx. 6.2 kg Communication Rack System x1 + Communication Rack System (extension) x1: Approx. 9.9 kg Communication Rack System x1 + Communication Rack System (extension) x2: Approx. 13.6 kg	Standard Rack System x1: Approx. 3.3 kg Standard Rack System x2: Approx. 6.5 kg Standard Rack System x3: Approx. 9.7 kg

Up to three racks can be combined and up to nine pumps can be attached at a time.
• TE-RS811 can be combined with the TERUFUSION Communication Rack System (TE-RS800)
• This product is compatible with EMC (electromagnetic compatibility) standard IEC 60601-1-2:2001 Amd. 1:2004 (CISPR group classification and class classification are Group 1 and Class B).
It is also compatible with the EMC level required by IEC 60601-2-24:1998
• Conformity standard
IEC 60601-1:1988,Amd1:1991,Amd2:1995
IEC 60601-1-1:2000
IEC 60601-1-2:2001,A1:2004
IEC 60601-1-6:2006
IEC 60601-2-24:1998
MDD (Medical Device Directive) 93/42/EEC (Class I)

TERUFUSION® One Touch Pole Clamp
(TE-877 / option)

Saves times affixing the clamp to the pole by a simple 3 step approach:

1. Grip the lever
2. Approach clamping point
3. Screw clamp to affix

TERUFUSION® Drip Sensor
(TE-977 / option)

The TERUFUSION Drip Sensor monitors activity inside the IV tube, alarming when free flow occurs or solution becomes empty.
(There is a limit to the detection capabilities of the IV probe.
In sudden free flow, when continual flow eliminates drips, the IV probe cannot detect them.)

TERUFUSION® Drug Library Manager
(TE-SW800B / option) *TE-LM800 only

TERUFUSION® Drug Software Package
(TE-SW800P / option) * TE-LM800 only

CE 0197

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ME13E-0307KL-II1 5/12 06JA

TERUMO®

Smart Infusion System

TERUFUSION® Infusion Pump Type LM Series
Syringe Pump Type SS Series

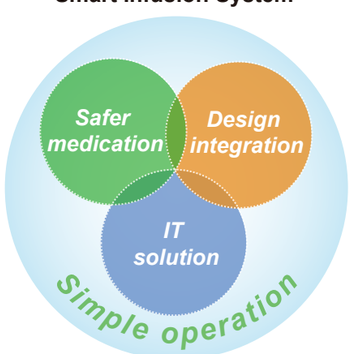
The simple way to get safe, high-precision infusion management

Smart Infusion System

Smart infusion system aims at more accurate, safer syringe pumps and infusion pumps.

- Smart pumps with leading-edge IT capabilities that connect them with hospital information and data systems, to take giant steps toward shared information and more accurate diagnosis.
- Standard pumps without IT functions: available for an incredible degree of accuracy and safety at eminently affordable prices.
- Choose the particular infusion system that best fits your operation.

Concept of Smart Infusion System



Smart Pumps (with IT function)

TERUFUSION® Infusion Pump Type LM TE-LM800
Midpress® type

TERUFUSION® Syringe Pump Type SS TE-SS800

Standard Pumps

TERUFUSION® Infusion Pump Type LM TE-LM700
Midpress® type

TERUFUSION® Syringe Pump Type SS TE-SS700

TERUFUSION® Communication Rack System

TE-RS800 (option)
With communication function

TE-RS811 (option)
Can be attached to TE-RS800

TERUFUSION® Standard Rack System

TE-RS700 (option)
Without communication function

Terumo smart infusion peripherals

Infusion set

TERUFUSION Type LM needs to be used with TERUFUSION Solution Administration Set for Infusion pump with AFF clip, or SURPLUG® Solution Administration Set with AFF clip, or TERUFUSION Blood Administration Set for Infusion pump with AFF clip.

Simple means no stress, no mistakes, no waste

Safer medication

Distinct easy-to-read 4.3-inch display

- Large 4.3-inch full-color monitor .
- Can be read clearly from some distance away.
- Screen reverses out when sleeping, clearly showing if the system's on or off.
- Alarm lamp for instant recognition

Full-color visual guidance for less experienced operators

- Visual guidance for less-experienced staff
- Follow it step by step to properly install and set up the pump.
- It's efficient and intuitive.
- The instructions are available in 19 languages.

Only seven buttons and a jog dial

- Simply, seven buttons and one jog dial let you control everything.
- Simple adjustments are done with the dial.

Infusion Pump TE-LM800

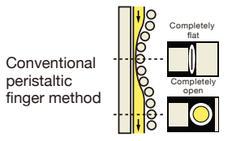
Sturdy construction

- Lid opens by hand. Sturdy, long-lasting construction.

Anti-free flow (AFF) function

- Reduces the risk of free flow
- Move the AFF clip to the lower auxiliary tube, it can be used as an automatic shut-off.

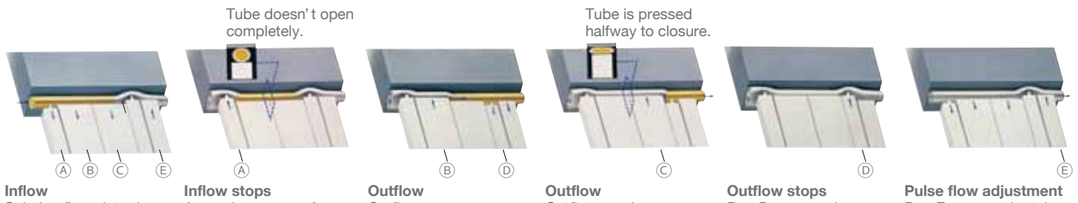

AFF clip



Conventional peristaltic finger method

Midpress — accurate infusion as well as transfusion

As its name suggests, midpress uses a finger to depress the middle of the tube, sending accurate and precise amounts of fluid into the IV tube. This method holds tube deformation to the absolute minimum. In addition to accurate infusion, midpress can also be used for blood transfusion with the addition of a transfusion kit.



Inflow
Solution flows into the tube.

Inflow stops
A certain amount of solution accumulates in the tube as part A presses against the tube.

Outflow
Outflow starts as part D opens and part B presses the tube.

Outflow
Outflow continues as part C presses the tube.

Outflow stops
Part D presses the tube fully.

Pulse flow adjustment
Part E presses the tube and completes outflow cycle.

Design integration

Compact racks save space

- Racks can handle up to three pumps at once, and up to three racks can be used in one stack (for 9 pumps in all).
- Power cords and infusion tubes stay out of the way so there' s more bedside room.


Pumps can be easily attached and removed while remaining attached to pole cramp.

Smart infusion workflow reduces safety worries

Data suggests that the biggest cause of error between prescription and drug administration is in the infusion time period*. An approach that works to eliminate human error is key to achieving high-quality healthcare. The advance pump with IT technology change methods of infusion and promote a simpler and safer way.

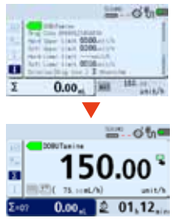
*Institute of Medicine of the National Academies (IOM)

IT solution

Smart Pumps [TE-LM800 / TE-SS800] only

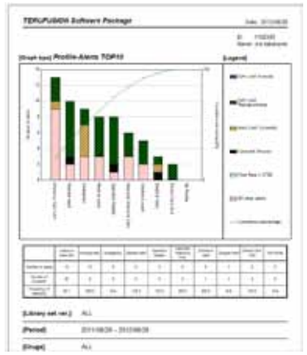
Aims to enhance safety and medication management regardless of operator's skill or experience

Drug library function eliminates human error and enhances medical management

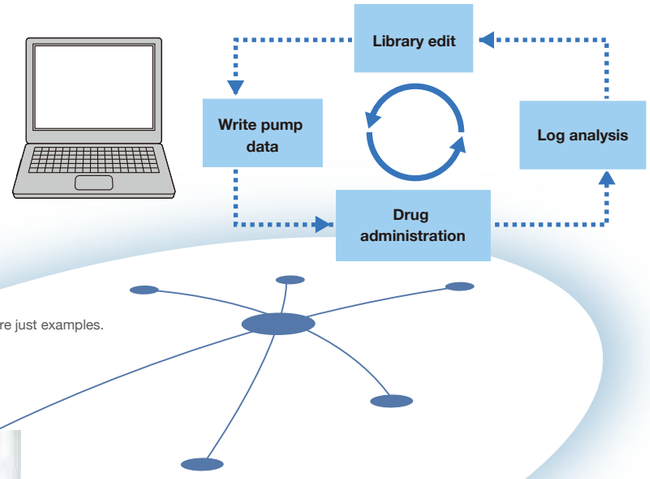


Once you select a drug you administer, medication information can be displayed. The actual medication can be confirmed by reference to the data. A combination of colors and patterns will make an operator recognizes drugs more easily in clinical situations. 16 combinations can be set in a drug library out of the 96 combinations in total as below.
- 32 colors
- 3 patterns (Plain/vertical, stripes/diagonal, stripes)

Continuous Quality Improvement (CQI)
- Maximum dosages can be reprogrammed easily if analysis of the data shows it is necessary.
- Allows continual improvement of daily infusion procedures.



- Compiles data on drug, consistency, infusion dose, etc.
- Just choose a drug name and the system does the rest.



Wrong drug infusion prevention

Not configurable	*20μg/kg/min*
Configurable if confirmed	*15μg/kg/min*
Configurable	*0 μg/kg/min*

*The figures provided are just examples.

- The maximum dosage of a drug can be set that prevents overdoses caused by data input mistakes.

Links with Hospital Information Systems (HIS)
- Medical personnel can access the patient's chart information from the nearest computer terminal.
- Data can be used in many different ways to further enhance medical services.

Product name	**TERUFUSION Infusion Pump Type LM**	**TERUFUSION Syringe Pump Type SS**
Model	TE-LM700/TE-LM800	TE-SS700/TE-SS800
Syringe size		5mL,10mL,20mL,30mL,50/60mL
Syringe brand		TERUMO or other specified brands
Dose mode	mL/h mode μg/kg/min mode* mg/kg/h mode* Library mode* (*: TE-LM800 only)	mL/h mode μg/kg/min mode* mg/kg/h mode* Library mode* (*: TE-SS800 only)
Flow rate setting range	• Setting range • When not using the drip sensor 0.10 to 1200.00 mL/h • When using the drip sensor 0.10 to 1200.00 mL/h (when setting is 20 drops/mL) 0.10 to 300.00 mL/h (when setting is 60 drops/mL) • Step 0.10 mL/h step (0.10 to 100.00 mL/h) * 1.00 mL/h step (100.00 to 1200.00 mL/h) * *: Step can be used when flow rate is set by the dial. (It will be 0.00 mL/h when the power is turned on.)	• Setting range 0.01 to 150.00 mL/h Note that the upper limit of the flow rate can be changed in the following ranges: 0.01 to 150.00 mL/h (when using syringe of 5 mL) 0.01 to 300.00 mL/h (when using syringe of 10, 20, 30 mL) 0.01 to 1200.00 mL/h (when using syringe of 50/60 mL) • Step 0.01 mL/h step (0.01 to 10.00 mL/h)* 0.10 mL/h step (10.00 to 100.00 mL/h)* 1.00 mL/h step (100.00 to 1200.00 mL/h)* *: Step can be used when flow rate is set by the dial. (It will be 0.00 mL/h when the power is turned on.)
Dose rate setting range	0.01 to 10.00 (0.01 step) 10.00 to 100.00 (0.10 step) 100.00 to 999.00 (1.00 step) (In units of such as μg/kg/min and mg/kg/h etc.) (It will be 0.00 when the power is turned on.) (TE-LM800 only)	0.01 to 10.00 (0.01 step) 10.00 to 100.00 (0.10 step) 100.00 to 999.00 (1.00 step) (In units of such as μg/kg/min and mg/kg/h etc.) (It will be 0.00 when the power is turned on.) (TE-SS800 only)
Weight setting range	0.1 to 300.0kg (0.1kg step) (TE-LM800 only)	0.1 to 300.0kg (0.1kg step) (TE-SS800 only)
Dilution setting range X	0.01 to 10.00 (0.01 step) 10.00 to 100.00 (0.10 step) 100.00 to 999.00 (1.00 step) (In units of such as mg/mL etc.) (TE-SS800 only)	0.01 to 10.00 (0.01 step) 10.00 to 100.00 (0.10 step) 100.00 to 999.00 (1.00 step) (In units of such as mg/mL etc.) (TE-SS800 only)
Volume delivered display range	0.00 to 10.00mL (0.01mL step) 10.00 to 100.00mL (0.10mL step) 100.00 to 9999.00mL (1.00mL step) When the dose rate is set in mass units, the volume is expressed in mass units. (VTBI setting range: 0.01 ng to 9999.99 kg) (It will be 0.00 mL/h when the power is turned on.)	0.00 to 10.00 mL (0.01 mL step) 10.00 to 100.00 mL (0.10 mL step) 100.00 to 9999.00 mL (1.00 mL step) When the dose rate is set in mass units, the volume is expressed in mass units. (VTBI setting range: 0.01 ng to 9999.99 kg) (It will be 0.00 mL/h when the power is turned on.)
Flow rate accuracy	Within ± 5% (The hourly precision after one hour has passed since the start of solution delivery, in the case where water or a physiological saline solution is used with a specified infusion set or blood transfusion set (hereinafter called "infusion set") at a constant flow rate of 1.00 mL/h or more (ambient temperature: 23±2) according to IEC 60601-2-24 standard.)	Mechanical accuracy: Within ±1% Accuracy including syringe: Within ±3% (Accuracy measured over 1 hour after starting infusion, and measured every hour thereafter, using Terumo syringe at a flow rate of 1.0mL/h or above)
Occlusion detection pressure	• Upper occlusion detection pressure -100 to -30 kPa • Lower occlusion detection pressure 30 to 120 kPa (set value) The lower occlusion detection pressure can be set in 10 levels.	10 to 120kPa (set value) The occlusion detection pressure can be set in 10 levels.
Purge flow rate	Approx. 500 mL/h	Approx. 150 mL/h (when using syringe of 5mL) Approx. 300 mL/h (when using syringe of 10mL) Approx. 400 mL/h (when using syringe of 20mL) Approx. 500 mL/h (when using syringe of 30mL) Approx. 1200 mL/h (when using syringe of 50/60mL)
Alarms	Upper Occlusion alarm, Lower Occlusion alarm, Pressure alarm*1, Air-in-line alarm, Door alarm, Flow Rate Abnormality alarm, Free Flow alarm, Line Empty alarm, Drip Sensor Dislocation alarm, Battery alarm, Re-alarm, Start Reminder, No Flow Rate alarm, No VTBI alarm, Flow Rate/VTBI Volume Judgment alarm, Completion alarm, Link Interruption alarm*1. *1: TE-LM800 only	Occlusion alarm, Pressure alarm*1, Nearly Empty alarm, Clutch Displacement alarm, Syringe Barrel Detection alarm, Syringe Displacement alarm, Plunger Displacement alarm, Battery alarm, Re-alarm, Start Reminder, No Flow Rate alarm, No VTBI alarm*2, Flow Rate/VTBI Volume Judgment alarm*2, Completion alarm*2, Link Interruption alarm*1 *1: TE-SS800 only*2: Only if the VTBI setting function is enabled (Default: disabled)
Safety functions	•Occlusion detection pressure select function •Air-in-line alarm sensitivity select function •Tube clamp function •Anti-free flow function •Flow rate range setting function A (Soft limits) •Flow rate range setting function B (Hard limits) •Key lock function	•Remaining volume detection position function •Occlusion detection pressure select function •Bolus reduction function •Flow rate range setting function A (Soft limits •Flow rate range setting function B (Hard limits) •Key lock function
Available functions	•Infusion set installation guidance function •Infusion set type display function •Infusion set drip volume select function •Drip volume display function •VTBI setting function •VTBI time setting function •Purge/bolus buzzer sound function •Volume delivered clear function •Standby function •Standby duration time select function •Buzzer volume select function •Switch operation buzzer sound function •Stop transition buzzer sound function •LCD brightness select function •Maintenance timer function •Date and time setting function •External communication function (RS-232C) (TE-LM702 only) •Free message function (TE-LM702 and 800 only) •External communication function (infrared communication (IrDA) (TE-LM800 only) •External communication function (wireless LAN) (TE-LM800 only) •Nurse call function (TE-LM702 only) •History function •AC power detector function •AC power detector buzzer sound function •Keep Vein Open function •Keep Vein Open flow rate select function •During-start volume delivered clear function •During-start flow rate/ dosage rate change function •Alarm melody select function •Setting step 100 times function •Hands on bolus function •Hands free bolus function •Shortcut call function •Night mode function •Power OFF buzzer sound function •Dose mode select function (TE-LM800 only) •Patient information display function (TE-LM800 only) •Intermittent dose function (TE-LM800 only) •Multi-step dose function (TE-LM800 only) •Delayed Start dose function (TE-LM800 only) •Link function (Switch function A, B) (TE-LM800 only) • Come and See ME function (TE-LM800 only) •Volume delivered unit select function (TE-LM800 only) •Micro notation select function (TE-LM800 only)	•Syringe installation •Syringe brand display function •Syringe type switch function •VTBI setting function •VTBI time setting function •Purge/bolus buzzer sound function •Volume delivered clear function •Standby function •Standby duration time select function •Buzzer volume select function •Switch operation buzzer sound function •Stop transition buzzer sound function •LCD brightness select function •Maintenance timer function •Date and time setting function •External communication function (RS-232C) (TE-SS702 only) •Free message function (TE-SS702 and 800 only) •External communication function (infrared communication (IrDA)) (TE-SS800 only) •External communication function (wireless LAN) (TE-SS800 only) •Nurse call function (TE-SS702 only) •History function •AC power detector function •AC power detector buzzer sound function •Keep Vein Open Function •Keep Vein Open flow rate select function •During-start volume delivered clear function •During-start flow rate/dosage rate change function •Alarm melody select function •Setting step 100 times function •Hands on bolus function •Hands free bolus function •Shortcut call function •Night mode function •Power OFF buzzer sound function •Dose mode select function (TE-SS800 only) •Patient information display function (TE-SS800 only) •Intermittent dose function (TE-SS800 only) •Multi-step dose function (TE-SS800 only) •Delayed Start dose function (TE-SS800 only) •Link function (Switch function A, B) (TE-SS800 only) •Come and See ME function (TE-SS800 only) •Volume delivered unit select function (TE-SS800 only) •Micro notation select function (TE-SS800 only)
Use conditions	Ambient temperature: 5 to 40 Relative humidity: 20 to 90%RH (non-condensing)	Ambient temperature: 5 to 40 Relative humidity: 20 to 90%RH (non-condensing)
Storage conditions	Ambient temperature: -20 to 45 Relative humidity: 10 to 95%RH (non-condensing)	Ambient temperature: -20 to 45 Relative humidity: 10 to 95%RH (non-condensing)
Transport conditions	Ambient temperature -20 to 60, Relative humidity 10 to 95%RH (non-condensing)	Ambient temperature -20 to 60 Relative humidity 10 to 95%RH (non-condensing)
Power supply	AC100 to 240V, 50 to 60Hz Internal battery (lithium ion battery) • Continuous use period: Approx. 5 hours (applies when solution is delivered continuously at 25 mL/h in ambient temperature of 25 with new fully charged battery) • Charging time: ≥8 hours (when charged with AC power supply with the power turned off) 28VA	AC100 to 240V, 50 to 60Hz Internal battery (lithium ion battery) • Continuous use period: Approx. 12 hours (applies when solution is delivered continuously at 5 mL/h in ambient temperature of 25 with new fully charged battery) • Charging time: ≥8 hours (when charged with AC power supply with the power turned off) 24VA
Power consumption classification	Class I equipment and internally powered equipment, type CF applied part, Continuous Operation, IP22 (Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.)	Class I equipment and internally powered equipment, type CF applied part, Continuous Operation, IP24
Dimensions	Without external communication (RS-232C): 253 mm (W)*2 x 120 mm (H)*2 x 102 mm (D)*3 With external communication (RS-232C): 253 mm (W)*2 x 120 mm (H)*2 x 121 mm (D)*3 *2: Excluding protrusions, *3: Excluding protrusions, pole clamp and moving range	Without external communication (RS-232C): 381 mm (W)*3 x 120 mm (H)*3 x 112 mm (D)*4 With external communication (RS-232C): 381 mm (W)*3 x 120 mm (H)*3 x 131 mm (D)*4 *3: Excluding protrusions, *4: Excluding protrusions, pole clamp and moving range
Unit weight	Approx. 2.0 kg	Approx. 2.0 kg

• This product is compatible with EMC (electromagnetic compatibility) standard IEC 60601-1-2:2001 Amd. 1:2004 (CISPR group classification and class classification are Group 1 and Class B). It is also compatible with the EMC level required by IEC 60601-2-24:1998.

• Conformity standard
IEC 60601-1:1988,Amd1:1991,Amd2:1995, IEC 60601-1-1:2000,
IEC 60601-1-2:2001,A1:2004, IEC 60601-1-6:2006, IEC 60601-1-8:2006, IEC 60601-2-24:1998, MDD (Medical Device Directive) 93/42/EEC (Class IIb)

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-12-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-12-23

M.Aihara

M.Sc. M. Aihara

Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki Aihara
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 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

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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.

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