Annexe I
Déclarations de conformité CE

EU DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
with Single Registration Number: JP-MF-000017478

being the manufacturer of:

TERUMO SYRINGE

[INFUSION AND IRRIGATION SYRINGES, SINGLE-USE]

Intended purpose:
This product is an apparatus used for injecting fixed amount of solution in the endermic, hypodermic, muscle tissues or blood vessels, or other body cavities, or sampling the blood or other body fluids, which can be used instantaneously and intended for use only once.

Basic UDI-DI: 498735037SS3X

Related product codes: See Appendix A (full list of active codes)

declare that the above product of **Class IIa** is in conformity with the applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the "Conformity assessment based on a quality management system and on assessment of technical documentation" set out in Annex IX, and by certification of Annex IX Chapter I & III (EU quality management system certificate number HZ 1485480-1), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the GERMAN Competent Authority and carrying the Notified Body No. 0197.

There is no reference to Common Specifications that have been used within the conformity assessment for Regulation (EU) 2017/745.

Authorised Representative: TERUMO EUROPE N.V.
Authorised Address: Interleuvenlaan 40, 3001 Leuven, BELGIUM
with Single Registration Number: BE-AR-000001433

This EU declaration of conformity is issued under our sole responsibility.

署名者:
hiroki sasagawa
署名者名: hiroki sasagawa
署名理由: この文書を承認する
署名時刻： 2025-06-12 | 3:00:42 午後 JST
3F7B1A275BA74182B04CDC2E69B7202D

Tokyo , 2025-06-12

(place and date of issue)

Hiroki Sasagawa
General Manager
Quality Assurance Department
For and on behalf of
TERUMO CORPORATION

Appendix A – Related product codes

Product code	UDI-DI
SS*02LE1	04987350702562
SS*02SE1	04987350708984
SS*02SE21161	04987350709004
SS*02SE21251	04987350709028
SS*02SE21381	04987350709042
SS*02SE22381	04987350709066
SS*02SE23251	04987350709080
SS*02SE23321	04987350709103
SS*02SE25161	04987350709127
SS*05LE1	04987350702609
SS*05SE1	04987350706324
SS*10LE1	04987350702647
SS*20ESE1	04987350700742
SS*20LE1	04987350749208
SS*30LE1	04987350701985
SS*30ESE1	04987350700766

Annexe II
Marquage CE

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1485480-1
Manufacturer:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
EUDAMED Single Registration No.:	JP-MF-000017478
Products:	Products of class Is: B019004 - BLOOD COMPONENTS SAMPLING BAGS AND KITS C900103 - PERCUTANEOUS ARTERIAL ACCESS HAEMOSTASIS SYSTEMS The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions Products of class IIa: A010101 - HYPODERMIC NEEDLES A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE C010101 - PERIPHERAL I.V. CATHETERS C030101 - EXTRACORPOREAL CIRCULATION KITS Z121799 - BLOOD TRANSFUSION INSTRUMENTS - OTHER A010102 - BUTTERFLY NEEDLES

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	150303725-307
Effective date:	2025-05-29
Expiry date:	2030-05-28
Issue date:	2025-04-25

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

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜVRheinland®
Precisely Right.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1485480-1
Manufacturer:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
EUDAMED Single Registration No.:	JP-MF-000017478

A019099 - NEEDLES FOR OTHER PROCEDURES - OTHER
G0399 - DIGESTIVE ENDOSCOPY DEVICES - OTHER
C040201 - PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES
C040202 - PERIPHERAL VASCULAR THERAPEUTIC GUIDEWIRES
C0504 - ARTERIAL INTRODUCTION SETS
A020199 - SYRINGES, SINGLE-USE - OTHER
C010402 - PERIPHERAL ANGIOGRAPHY DEVICES
B020101 - BED-SIDE LEUKOREDUCTION FILTERS
V010402 - LANCETS WITHOUT SAFETY SYSTEMS, SINGLE-USE

Products of class IIb:
B010202 - BLOOD TRANSFER BAGS AND KITS PLATELETS CONCENTRATE TRANSFER BAGS AND KITS
B010201 - BLOOD TRANSFER BAGS AND KITS WHOLE BLOOD, RED BLOOD CELLS OR PLASMA TRANSFER BAGS AND KITS
Z120303 - INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
INFUSION INSTRUMENTS

Report No.:	150303725-307
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EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1485480-1
Manufacturer:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan
EUDAMED Single Registration No.:	JP-MF-000017478
	B020102 - LEUKOREDUCTION FILTERS LABORATORY LEUKOREDUCTION FILTERS B010102 - BLOOD COLLECTION BAGS AND KITS HOMOLOGOUS DONOR BLOOD COLLECTION BAGS AND KITS Products of class III: C010401 - ANGIOGRAPHY AND HAEMODYNAMIC DEVICES CARDIAC ANGIOGRAPHY DEVICES C0504 - CARDIOVASCULAR INTRODUCER SHEATHS ARTERIAL INTRODUCTION SETS C0499 - CARDIOVASCULAR GUIDEWIRES CARDIOVASCULAR GUIDEWIRES – OTHER
Authorized representative(s):	Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium Terumo BCT Europe N.V. Ikaroslaan 41 1930 Zaventem Belgium
Report No.:	150303725-307
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Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1485480-1
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EUDAMED Single Registration No.:	JP-MF-000017478

Certificate history		
Revision:	Description:	Issue date:
25	Re-certification Replaces certificate HZ 1485480-1 Rev. 24 issued 2024-12-18	2025-04-25

Report No.:	150303725-307
Effective date:	2025-05-29
Expiry date:	2030-05-28
Issue date:	2025-04-25

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

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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www.zlg.de
BS-MDR-091

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Annexe III
Certificat EN ISO 13485 :2016

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 1485480-1
Certificate Holder:	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 - 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 - Intravascular Imaging Catheter and Accessories - Intravascular Imaging System and Accessories - Intravenous Catheter

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.:	150291641-301
Effective date:	2024-07-02
Expiry date:	2026-08-29
Issue date:	2024-07-02

Replaces certificate SX 1485480-1 issued 2023-07-20

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

This certificate can be validated on https://www.certipedia.com

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

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Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 1485480-1
Certificate Holder:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, 151-0072 Japan

- 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 prosthesis and Accessories
- Wearable Infusion Pump

Report No.:	150291641-301
Effective date:	2024-07-02
Expiry date:	2026-08-29
Issue date:	2024-07-02

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

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

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Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 1485480-1
Certificate Holder:	Terumo Corporation 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, 151-0072 Japan

The scope of certification also covers the following sites:

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, Service 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.:	150291641-301
Effective date:	2024-07-02
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Issue date:	2024-07-02

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