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
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
	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
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

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

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.