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 A010601 - CARPULE NEEDLES A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE C010101 - PERIPHERAL I.V. CATHETERS C030101 - EXTRACORPOREAL CIRCULATION KITS Z121799 - BLOOD TRANSFUSION INSTRUMENTS - OTHER

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.:	150243724-320
Effective date:	2024-02-29
Expiry date:	2025-05-28
Issue date:	2024-02-29

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
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A010102 - BUTTERFLY NEEDLES
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

Products of class IIb:
B010202 - BLOOD TRANSFER BAGS AND KITS
PLATELETS CONCENTRATE TRANSFER BAGS AND KITS
Intended Purpose: TERUFLEX BP-KIT with IMUGARD III-SPL is intended for pooling up to six buffy-coats, for in process filtration and preservation of leukocyte removed platelet concentrate.
B010202 - BLOOD TRANSFER BAGS AND KITS
PLATELETS CONCENTRATE TRANSFER BAGS AND KITS
Intended Purpose: TERUFLEX BP-KIT is intended for pooling up to six buffy-coats, for in process separation and

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preservation of platelet concentrates.
B010201 - BLOOD TRANSFER BAGS AND KITS
WHOLE BLOOD, RED BLOOD CELLS OR PLASMA TRANSFER BAGS AND KITS
Intended Purpose: TERUFLEX TRANSFER BAG is intended for separating and storing each blood component.
Z120303 - INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
INFUSION INSTRUMENTS
Intended Purpose: TERUFUSION TE-18 is an infusion pump intended for the controlled delivery of parenteral nutrition, fluid maintenance, which is conducted by healthcare professionals, in a clinical environment.
B020102 – LEUKOREDUCTION FILTERS
LABORATORY LEUKOREDUCTION FILTERS
Intended Purpose: IMUGARD III-RC is intended for the removal of leukocytes from a single unit of packed red blood cells or whole blood.

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Products of class III:
C010401 - ANGIOGRAPHY AND HAEMODYNAMIC DEVICES
CARDIAC ANGIOGRAPHY DEVICES
Intended Purpose: Use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or a catheter into the target site.
Intended Purpose: Heartrail II Guiding Catheter is designed for the introduction of interventional devices and for the delivery of radio-opaque media into selected sites in the vascular system.
C0504 - CARDIOVASCULAR INTRODUCER SHEATHS
ARTERIAL INTRODUCTION SETS
Intended Purpose: The device is intended to be inserted percutaneously into a vessel to facilitate the insertion of angiographic, electrode, balloon, or similar catheters.
C0499 - CARDIOVASCULAR GUIDEWIRES
CARDIOVASCULAR GUIDEWIRES – OTHER
Intended Purpose: The device is intended to direct a catheter to the desired anatomical location in the vascular system during diagnostic or interventional procedures.

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Authorized representative(s):	Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium Terumo BCT Europe N.V. Ikaroslaan 41 1930 Zaventem Belgium

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Certificate history		
Revision:	Description:	Issue date:
0	Initial	2020-05-29
1	Added product (C030101)	2021-05-07
2	Added product (Z121799) and Authorised representative	2022-03-29
3	Added product (A010102)	2022-04-28
4	Added product (B010202)	2022-07-25
5	Added product (A019099)	2022-08-01
6	Added product (B019004)	2022-08-24
7	Minor amendment of Intended Purpose (B010202) & Added product (C010401)	2022-12-21
8	Added product (B010202) of different Intended Purpose	2023-02-20
9	Added product (C900103)	2023-03-29
10	Added Product (G0399)	2023-07-28
11	Added Product (B010201)	2023-08-15
12	Added product (C040201, C040202)	2023-08-30
13	Added product (C0504, class III)	2023-09-25
14	Added product (C0504, class IIa)	2023-10-13
15	Added product (A020199)	2023-11-22

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Revision:	Description:	Issue date:
16	Added product (Z120303)	2023-12-12
17	Added product (C010402)	2023-12-25
18	Added product (B020102)	2024-01-12
19	Added product (C0499)	2024-02-06
20	Added Intended purpose (Class III C010401)	2024-02-29

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