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:

CAPIOX FX

[EXTRACORPOREAL CIRCULATION KITS]

Intended purpose:

CAPIOX FX25

The CAPIOX FX25 is intended to be used during open heart surgical procedures requiring cardiopulmonary bypass for periods up to 6 hours. The CAPIOX FX25 is for use with patients when required blood flow rate will not exceed 7L/min. The CAPIOX FX25 Hardshell Reservoir is also intended for use in vacuum assisted venous drainage procedure, in post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement. The Integral Arterial Filter is intended to filtrate non-biologic particles and emboli and to facilitate gaseous emboli removal from the blood flowing through a cardiopulmonary bypass circuit. This device shall only be used by properly trained and qualified personnel.

CAPIOX FX15

The CAPIOX FX15 is intended to be used during open heart surgical procedures requiring cardiopulmonary bypass for periods up to 6 hours. The CAPIOX FX15 is for use with patients when required blood flow rate will not exceed 5 L/min (4 L/min if using product codes CX*FX15RW30 or CX*FX15RE30). The CAPIOX FX15 Hardshell Reservoir is also intended for use in vacuum assisted venous drainage procedure, in post-operative chest drainage and autotransfusion procedures to aseptically return the blood to the patient for blood volume replacement. The Integral Arterial Filter is intended to filtrate non-biologic particles and emboli and to facilitate gaseous emboli removal from the blood flowing through a cardiopulmonary bypass circuit. This device shall only be used by properly trained and qualified personnel.

CAPIOX FX05

The CAPIOX FX05 is intended to be used during open heart surgical procedures to transfer oxygen and remove carbon dioxide from blood and to control the blood temperature during cardiopulmonary bypass for periods up to 6 hours. The CAPIOX FX05 is a NEONATE, INFANT oxygenator intended for use in procedures up to maximum flow of 1.5 L/min. The patient weight and BSA should be considered upon use. The FX05 Hardshell Reservoir is also intended for use in vacuum assisted venous drainage procedures. The Integral Arterial Filter is intended to filtrate non-biologic particles and emboli and to facilitate gaseous emboli removal from the blood flowing through a cardiopulmonary bypass circuit. This device shall only be used by properly trained and qualified personnel.

Rev. 02
DoC No. DOC-DC-0094238
Reference to. DC-0094238

Basic UDI-DI: 498735026CXFXP6

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 to 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.

DocuSigned by:
Signer Name: Toshio Nakashima
Signing Reason: I approve this document
Signing Time: 2024-02-29 | 9:53:17 午前 JST
7CB53CAEA6904D2895AFA45B61783210

Tokyo , 2024-02-29
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
For and on behalf of
TERUMO CORPORATION

Appendix A – Related product codes

Product code	UDI-DI
CX*FX25E	04987350701060
CX*FX25W	04987350701084
CX*FX25RE	04987350701022
CX*FX25RW	04987350701046
CX*FX15E	04987350701183
CX*FX15W	04987350701206
CX*FX15RE30	04987350701145
CX*FX15RE40	04987350701107
CX*FX15RW30	04987350701169
CX*FX15RW40	04987350701121
CX*FX05E	04987350781710
CX*FX05W	04987350781734
CX*FX05RE	04987350781758
CX*FX05RW	04987350781772

DocuSign

完了証明書

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ステータス: 完了

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