TERUMO

No.DOC-DQ010- 0639

Rev.06

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

CAPIOX FX

Product : Extra-corporeal Membrane Oxygenator

declare that the above products of **Class IIa** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60121893 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, August 30, 2017
(place and date of issue)

Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

Digitally signed by Grabazei Alexandru
Date: 2020.04.30 14:09:32 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A - List of Code Number Structure

C	X	*	F	X	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11

Character number	Character & Meaning
1,2,4,5	Product name CAPIOX FX
3	Destination * : for export
6-7	Effective fiber surface area 25 : approx. 2.5m^2 05 : approx. 0.5m^2 15 : approx. 1.5m^2
8	Availability of hardshell venous reservoir R : Available Blank : Not available
9	Reserve W : Blood outlet port orientation is left when water ports faces this side. E : Blood outlet port orientation is right when water ports faces this side.
10-11	Types of hardshell venous reservoir *1 30 : With 3000mL Reservoir 40 : With 4000mL Reservoir *1 FX15 only