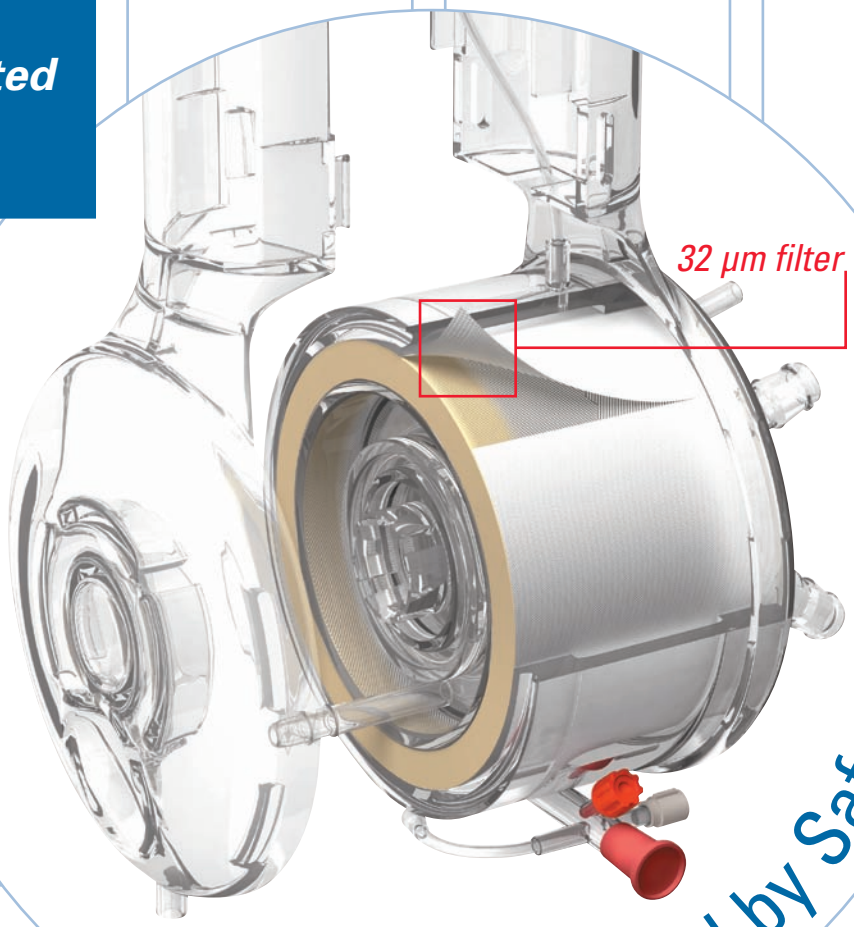
CAPIOX® FX Family of Oxygenators with Integrated Arterial Filter

Breakthrough technology for added patient safety

With integrated filter!



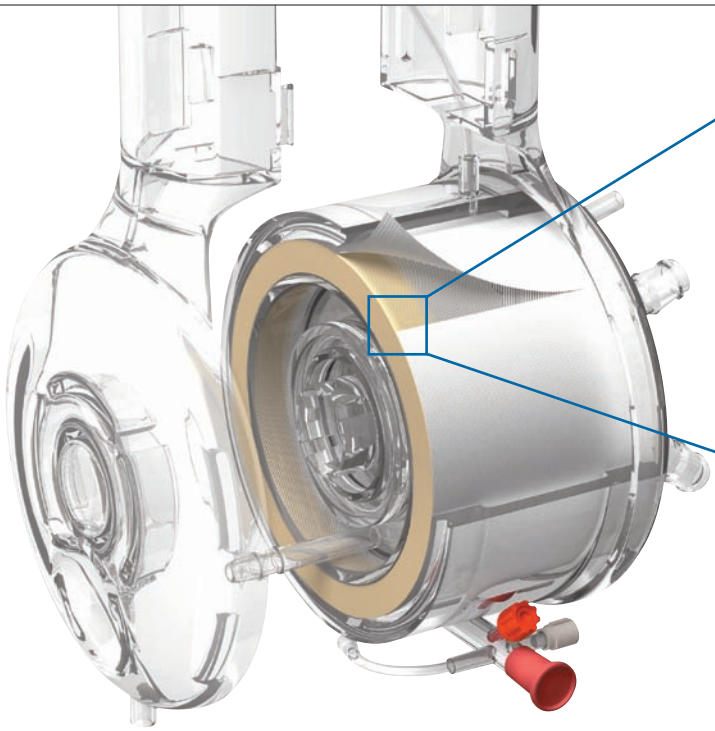
Surrounded by Safety

TERUMO®

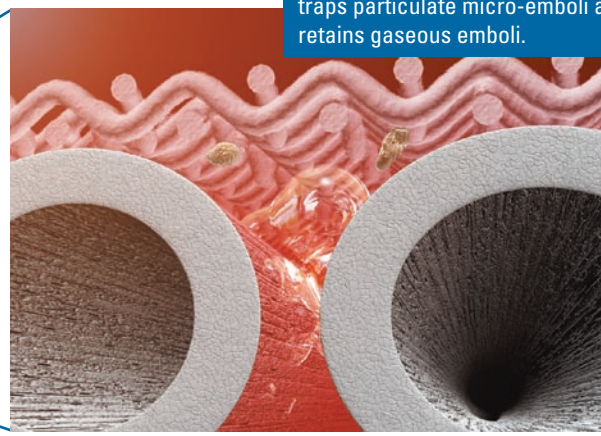
CAPIOX® FX Family of Oxygenators

Integrated arterial filter with self-venting technology

A 32 µm screen filter surrounds the fiber layer of the oxygenator. Particulate micro-emboli that may be present in the blood are trapped in the filter mesh while gaseous emboli remain inside the oxygenator and in contact with the hollow fibers. Driven by the pressure difference, gaseous emboli enter the inner lumen of the microporous hollow fiber and are eliminated via the gas outlet.

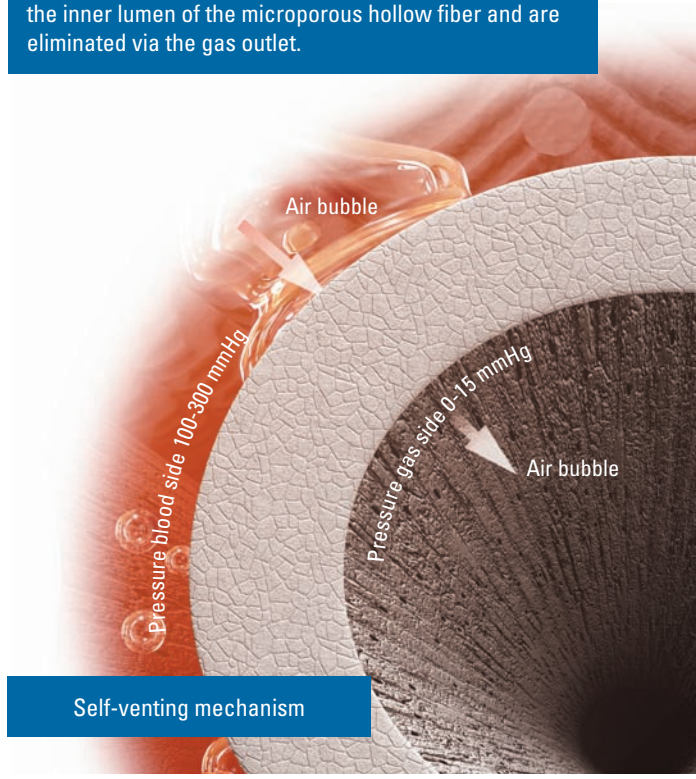


Screen filter surrounds the fiber layer, traps particulate micro-emboli and retains gaseous emboli.



Driven by the pressure difference between the blood side and gas side of the oxygenator, gaseous emboli enter the inner lumen of the microporous hollow fiber and are eliminated via the gas outlet.

Filter Pore Size 32 µm



Self-venting mechanism

Xcoating™, *Terumo's own biocompatible amphiphilic polymer surface coating, is a standard feature of all CAPIOX® FX oxygenators.*

Integrated arterial filter

- Filter inside oxygenator housing
- 32 µm pore size
- Self-venting technology

CAPIOX® FX05 Oxygenator

For neonates and infants

Oxygenator

Proven performance

- Fully integrated arterial filter with self-venting technology
- Low priming volume, high gas exchange and low pressure drop are optimally balanced for superb performance
- Hollow fibers manufactured exclusively by Terumo using a patented technology means total quality management from raw materials to finished product
- Woven fiber bundle ensures consistent and high-performance gas exchange
- Choice of blood outlet port configurations for easy access and increased circuit flexibility
- No DEHP used in PVC tubing

Hardshell Reservoir

Full featured

- Elongated shape provides stable blood flow path and enhanced visibility at all levels from all angles
- Rotating venous inlet improves set-up flexibility
- Connecting mount increases flexibility in circuit set-up and oxygenator rotation
- Funnel-shaped cardiotomy filter improves breakthrough and residual volumes
- No DEHP used in PVC tubing

- *Maximum blood flow: 1.5 L/min*
- *Oxygenator priming volume: 43 mL*
- *Arterial filter surface area: 130 cm²*
- *Reservoir storage capacity: 1000 mL*

West outlet port
Oxy inlet on right when outlet is facing away from user

East outlet port
Oxy inlet on left when outlet is facing away from user

Choose the blood outlet port configuration that best suits your circuit

CAPIOX® FX15 Oxygenator

For children, small adults and minimized circuits

Available in two reservoir sizes

- Maximum blood flow: 4.0 L/min
- Oxygenator priming volume: 144 mL
- Arterial filter surface area: 360 cm^2
- Reservoir storage capacity: 3000 mL

- Maximum blood flow: 5.0 L/min
- Oxygenator priming volume: 144 mL
- Arterial filter surface area: 360 cm^2
- Reservoir storage capacity: 4000 mL

CAPIOX® FX25 Oxygenator

For all adults

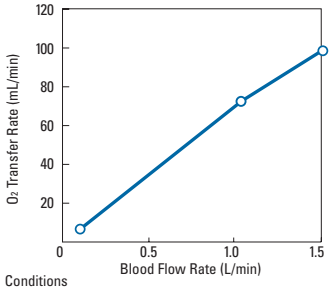
- Maximum blood flow: 7.0 L/min
- Oxygenator priming volume: 260 mL
- Arterial filter surface area: 600 cm^2
- Reservoir storage capacity: 4000 mL

TOTM – an alternative plasticizer

Terumo is ever striving to develop new medical technologies with minimal negative impact to patients and the environment. In line with this goal, Terumo provides an alternative plasticizer for the manufacturing of its products. TOTM (trioctyl trimellitate) offers outstanding physical properties (such as flexibility) to the material and low plasticizer elution.

CAPIOX FX05 Performance Data

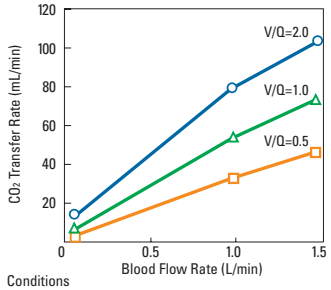
O_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4	V/Q	= 1.0

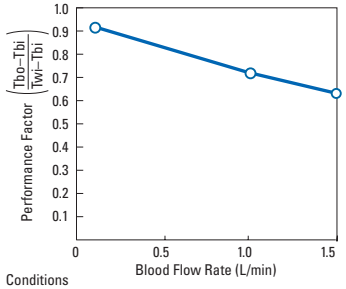
CO_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1 g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4		

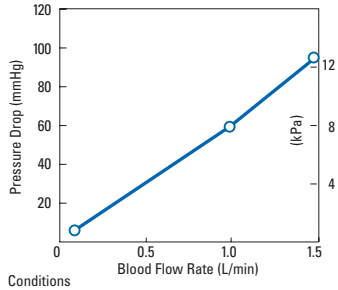
Heat Exchanger Performance Factor (in vitro)



Conditions

Blood	= Bovine		
Hb	= 12 ± 1 g/dL	Twi	= 40 ± 1°C
Tbi	= 30 ± 1°C	Water flow rate	= 15 L/min

Blood Side Pressure Drop (in vitro)

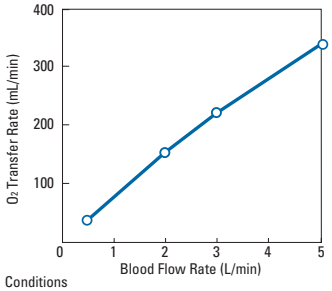


Conditions

Blood	= Bovine
Hb	= 12 ± 1 g/dL
Temp	= 37 ± 1°C

CAPIOX FX15 Performance Data

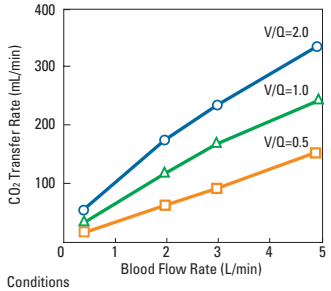
O_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4	V/Q	= 1.0

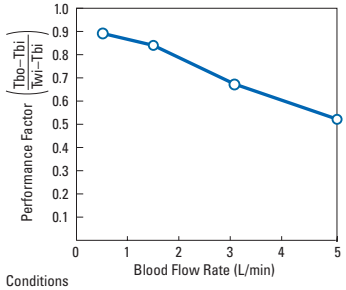
CO_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1 g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4		

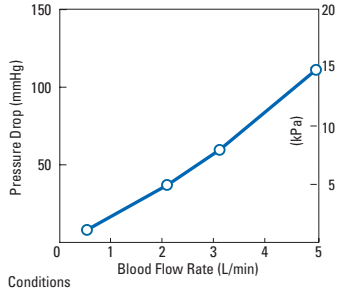
Heat Exchanger Performance Factor (in vitro)



Conditions

Blood	= Bovine	Twi	= 40 ± 1°C
Hb	= 12 ± 1 g/dL	Water flow rate	= 15 L/min
Tbi	= 30 ± 1°C		

Blood Side Pressure Drop (in vitro)

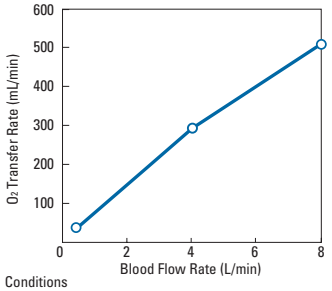


Conditions

Blood	= Bovine	B.E.	= 0 ± 5 mEq/L
Hb	= 12 ± 1 g/dL	Temp	= 37 ± 1°C

CAPIOX FX25 Performance Data

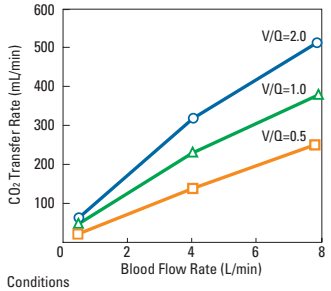
O_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4	V/Q	= 1.0

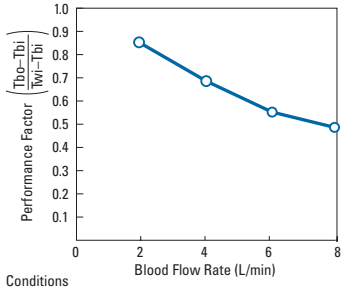
CO_2 Transfer Rate (in vitro)



Conditions

Blood	= Bovine	SvO_2	= 65 ± 5%
Hb	= 12 ± 1 g/dL	$PvCO_2$	= 45 ± 5 mmHg
Temp	= 37 ± 1°C	B.E.	= 0 ± 5 mEq/L
pH	= 7.4		

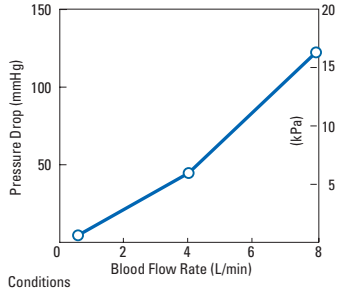
Heat Exchanger Performance Factor (in vitro)



Conditions

Blood	= Bovine	Twi	= 40 ± 1°C
Hb	= 12 ± 1 g/dL	Water flow rate	= 15 L/min
Tbi	= 30 ± 1°C		

Blood Side Pressure Drop (in vitro)



Conditions

Blood	= Bovine	B.E.	= 0 ± 5 mEq/L
Hb	= 12 ± 1 g/dL	Temp	= 37 ± 1°C

Holder Systems

CAPIOX FX05 Oxygenator

Order # XX*CXH05R

Order # XX*CXH05

CAPIOX FX15 and CAPIOX FX25 Oxygenators

Order # 801804
XX*CXH18R (Europe only)

Order # 801139
XX*XH032 (Europe only)

Order # 812613 for FX25 (US only)
812614 for FX15 (US only)
XX*CXH15 (Europe only)

CAPIOX FX Family of Oxygenators

Specifications

Oxygenator

Material		
	Housing	Polycarbonate
	Fibers	Microporous polypropylene
	Heat exchanger	Stainless steel

Oxygenator	FX05	FX15	FX25
Fiber bundle surface area	Approx. 0.5 m^2	Approx. 1.5 m^2	Approx. 2.5 m^2
Heat exchanger surface area	Approx. 0.035 m^2	Approx. 0.14 m^2	Approx. 0.2 m^2
Blood flow range	0.1 – 1.5 L/min	0.5 – 5.0 L/min, 0.5 – 4.0 L/min (with R30)	0.5 – 7.0 L/min
Reference blood flow (AAMI std.)	2.5 L/min	7.0 L/min	n.a.
Priming volume (static)	43 mL	144 mL	260 mL
Blood inlet port (from pump)	1/4" (6.4 mm)	3/8" (9.5 mm)	
Blood outlet port	1/4" (6.4 mm)	3/8" (9.5 mm)	
Cardioplegia port	–	1/4" (6.4 mm)	
Luer port (for recirc. or blood cardioplegia)	One luer lock on blood outlet port	n.a.	
Gas inlet port	1/4" (6.4 mm)		
Gas outlet port	5/16" (7.9 mm)	1/4" (6.4 mm)	
Water ports	1/2" (12.7 mm) Hansen quick-connect fittings		
Maximum pressure Blood inlet	1000 mmHg (133 kPa)		
Maximum pressure Water inlet	2 kgf/cm^2 (196 kPa) (28.5 psi)		
Arterial filter			
Filter material	Polyester screen type		
Pore size	32 µm		
Surface area	130 cm^2	360 cm^2	600 cm^2

Hardshell Reservoir

Material		
	Housing	Polycarbonate
	Venous filter	Polyester screen type, Pore size 47 µm
	Cardiotomy filter	Polyester depth type
	Defoamer	Polyurethane foam

Hardshell reservoir	FX05	FX15 R30 (for FX15)	FX15 R40 (for FX15)	FX25
Blood flow range Venous flow Cardiotomy inlet Combined flow	0.1 – 1.5 L/min Max. 1.5 L/min Max. 1.5 L/min	0.5 – 4.0 L/min Max. 4.0 L/min Max. 4.0 L/min	0.5 – 5.0 L/min Max. 5.0 L/min Max. 5.0 L/min	0.5 – 7.0 L/min Max. 5.0 L/min Max. 7.0 L/min
Blood storage capacity	1000 mL	3000 mL	4000 mL	4000 mL
Min. operating volume	15 mL	70 mL	200 mL	200 mL
Venous blood inlet port	1/4" (6.4 mm) rotatable	3/8" (9.5 mm) rotatable	1/2" (12.7 mm) rotatable	1/2" (12.7 mm) rotatable
Blood outlet port (to pump)	1/4" (6.4 mm)	3/8" (9.5 mm)		
Suction ports	Five 3/16" – 1/4" (4.8 mm – 6.4 mm) rotatable	Six 1/4" (6.4 mm)		
Vertical port (to CR filter)	n.a.	3/8" (9.5 mm)		
Quick prime port	1/4" (6.4 mm)			
Vent port	1/4" (6.4 mm)			
Auxiliary port	1/4" – 3/8" (6.4 mm – 9.5 mm)			
Luer ports	Three filtered luer locks to cardiotomy filter, one non-filtered luer lock, two luer locks on venous inlet			
Maximum sustainable negative pressure in reservoir	-150 mmHg (-20.0 kPa)			

Ordering Information

DESCRIPTION	CATALOG NO.	UNITS/CASE
CAPIOX FX05 Oxygenator		
Oxygenator with integrated arterial filter[1]	CX*FX05W	4
Oxygenator with integrated arterial filter[1]	CX*FX05E	4
Oxygenator with integrated arterial filter/hardshell reservoir[2]	CX*FX05RW	4
Oxygenator with integrated arterial filter/hardshell reservoir[2]	CX*FX05RE	4
CAPIOX FX15 Oxygenator		
Oxygenator with integrated arterial filter[3]	CX*FX15W	4
Oxygenator with integrated arterial filter[3]	CX*FX15E	4
Oxygenator with integrated arterial filter/hardshell reservoir[4]	CX*FX15RW30	2
Oxygenator with integrated arterial filter/hardshell reservoir[4]	CX*FX15RE30	2
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX15RW40	2
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX15RE40	2
CAPIOX FX25 Oxygenator		
Oxygenator with integrated arterial filter	CX*FX25W	4
Oxygenator with integrated arterial filter	CX*FX25E	4
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX25RW	2
Oxygenator with integrated arterial filter/hardshell reservoir	CX*FX25RE	2

DESCRIPTION	CATALOG NO.	UNITS/CASE
Holders for CAPIOX FX Oxygenators		
Holder for FX05 oxygenator	XX*CXH05	1
Holder for FX05 oxygenator with hardshell reservoir	XX*CXH05R	1
Adapter for SX holder for FX05	XX*CXH05AD	1
Holder for FX15/25 oxygenator with hardshell reservoir (short arm)	801139	1
Holder for FX15/25 oxygenator with hardshell reservoir (long arm)	801804	1
Holder for FX25 oxygenator (US only)	812613	1
Holder for FX15 oxygenator (US only)	812614	1
Holder for FX15/25 oxygenator (Europe only)	XX*CXH15	1
Holder for FX15/25 oxygenator when separated from reservoir	XX*CXH25F	1
Holder for FX15/25 oxygenator with hardshell reservoir (Europe only)	XX*CXH18R	1
Holder for FX15/25 oxygenator with hardshell reservoir, short arm (Europe only)	XX*XH032	1

[1] Contains 2 adapters 3/16" – 1/4" and a recirculation line
[2] Contains 4 adapters 3/16" – 1/4", 1 adapter 1/4" – 3/8" and a recirculation line
[3] Contains 2 adapters 1/4" – 3/8"
[4] Contains 4 adapters 1/4" – 3/8"

TERUMO®

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
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800 521 2818 toll free
www.terumo-cvs.com

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Interleuvenlaan 40
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www.terumo-europe.com

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Miami, Florida 33178
USA
305 477 4822 phone
305 477 4872 fax
800 283 7866 toll free

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Tokyo 151-0072
Japan
81 3 3374 8111 phone
81 3 3374 8196 fax
www.terumo.com

CV01FXFAMGB-0109FKFK-I5(01.09)E

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
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
- Endoscopic Vessel Harvesting System
- 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

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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- 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 Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

The scope of certification also covers the following:

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 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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
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
- Endoscopic Vessel Harvesting System
- 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

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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization:
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- 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 Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization: Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-ku, Tokyo
151-0072 Japan

The scope of certification also covers the following:

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 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.: 150241635-301
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Holds Certificate No: **FM 584812**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and Development, Manufacturing and Distribution of Blood Oxygenators, Centrifugal Pumps, Cardioplegia Delivery Sets, Cardiovascular Procedure Kits, Pressure Relief Valves, CDI Cuvettes, CDI Shunt Sensors, CDI Calibration Gases, Blood Reservoirs and Endoscopic Vessel Harvesting Systems, On and Off Pump Coronary Artery Bypass Graft Instruments/Devices and Accessories.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-05-08
Latest Revision Date: 2021-10-13

Effective Date: 2021-10-15
Expiry Date: 2024-10-14

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 584795**

Issued To: **Terumo Cardiovascular Systems Corporation**
125 Blue Ball Rd
Elkton
Maryland
21921
USA

In respect of:

Design, Development and Manufacture of Sterile Blood Oxygenators, Centrifugal Pumps, Cardioplegia Delivery Sets, Pressure Relief Valves, Cuvettes, Shunt Sensors, Blood Reservoirs, Vessel Harvesting Systems, Devices for heart stabilization and positioning for use in open heart surgery.

Those aspects of Annex II related to securing and maintaining Sterility in the manufacture of the suture holder.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2012-05-31** Date: **2021-05-17** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 584795

Issued To:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Number	Device Name	Intended purpose per IFU
Class III		
---	CDI Shunt Sensors	See CE 586827
Class IIb		
MD1104	Vessel Harvesting System	The VirtuoSaph Plus Endoscopic Vessel Harvesting System VSP550EX is indicated for use in minimally invasive surgery allowing access for vessel harvesting and is indicated for adult patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for adult patients requiring blunt dissection of tissue including dissection of blood vessels of the extremities. Extremity procedures include tissue dissection and/or vessel harvesting along the saphenous vein for coronary artery and peripheral artery bypass. The radial artery is only used for coronary artery bypass.

First Issued: **2012-05-31** Date: **2021-05-17** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 584795

Issued To:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD0102	Cardio Pulmonary ByPass Circuit and Cardioplegia Accessories	---
MD0106	Devices for heart stabilization and positioning	---
Class Is		
MD0106	Suture Holder	---

First Issued: **2012-05-31** Date: **2021-05-17** Expiry Date: **2024-05-26**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 584795**
Date:	**2021-05-17**
Issued To:	**Terumo Cardiovascular Systems Corporation** **125 Blue Ball Rd** **Elkton** **Maryland** **21921** **USA**

Subcontractor:	**Service(s) supplied**
Aomori Olympus Co., Ltd 2-248-1, Okkonoki Kuroishi-Shi AOMORI 036-0357 Japan	**Manufacture**
Indo-MIM Pvt. Ltd. Plot #45 (P) KIADB Industrial Area Hoskote Bangalore 562 114 Karnataka India	**Manufacture**
Isomedix Operations, Inc. 435 Whitney Street Northborough Massachusetts 01532 USA	**ETO Sterilization**

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 584795**

Date: **2021-05-17**

Issued To: **Terumo Cardiovascular Systems Corporation**
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Subcontractor:	**Service(s) supplied**
Sterigenics EO Canada, Inc. 781 Pharmacy Avenue Toronto Ontario M1L3K2 Canada	**ETO Sterilization**
Sterigenics US, LLC 344 Bonnie Circle Corona California 92880 USA	**Radiation (Gamma Sterilization)**
Sterigenics US, LLC 2311 Lincoln Avenue Hayward California 94545 USA	**Radiation (Gamma Sterilization)**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 584795**
Date:	**2021-05-17**
Issued To:	**Terumo Cardiovascular Systems Corporation** **125 Blue Ball Rd** **Elkton** **Maryland** **21921** **USA**

Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 84 Park Road Queensbury New York 12804 USA	**ETO Sterilization**
Surmodics, Inc. 9924 West 74th Street Eden Prairie Minnesota 55344 USA	**Crucial Supplier**
Terumo Cardiovascular Systems Corp. 6200 Jackson Road Ann Arbor Michigan 48103 USA	**Design** **Development**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 584795**
Date:	**2021-05-17**
Issued To:	**Terumo Cardiovascular Systems Corporation** **125 Blue Ball Rd** **Elkton** **Maryland** **21921** **USA**

Subcontractor:	**Service(s) supplied**
Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium	**EU Representative**
Terumo Medical Corporation 950 Elkton Boulevard Elkton MD 21921 USA	**Radiation (Gamma Sterilization)**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 584795**

Date: **2021-05-17**

Issued To: **Terumo Cardiovascular Systems Corporation**
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Date	Reference Number	Action
31 May 2012	7805751	First issue. Transfer from another Notified Body.
14 August 2014	8180239	Extend scope to include devices for heart stabilization and positioning for use in open heart surgery; Remove "Cardiovascular Procedure Kits" from Scope. Add subcontractors relevant to heart stabilization and positioning devices: ARMM,Inc., Indo-US MIM Tec Pvt. Ltd., and Sterigenics Hayward, and Corona sites.
29 May 2015	8184532	Scope updated from "Endoscopic Vein Harvesting Systems" to "Endoscopic Vessel Harvesting Systems".
09 February 2017	8630231	Certificate renewal. Word 'sterile' added to scope. Crucial supplier SurModics added. Significant subcontractors ARMM Inc in California USA, Sterigenics US LLC in New Jersey USA and Sterigenics in NC USA removed. Administrative changes.
13 February 2019	7843590	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 584795**

Date: **2021-05-17**

Issued To: **Terumo Cardiovascular Systems Corporation**
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Date	Reference Number	Action
15 May 2020	9749499	Certificate renewal Addition of device table Update to certificate scope: - Removal of arterial filters - Removal of CDI from cuvettes and shunt - Removal of CDI calibration gases - Removal of Endoscopic from vessel harvesting systems - Removal of associated sterile and non-sterile accessories. - Addition of "Those aspects of Annex II related to securing and maintaining Sterility in the manufacture of the suture holder." Updates to certificate subcontractors: - Removal of Olympus Winter - Administrative correction in name and address of Indo-MIM Pvt. Ltd. - Replaced Road with Boulevard in address of Terumo Medical Corporation subcontractor.
17 May 2021	3430430	Addition of sterilization subcontractor Sterigenics EO Canada, Inc. for the Terumo Capiox Oxygenators / Reservoirs.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 584795**

Date: **2021-05-17**

Issued To: **Terumo Cardiovascular Systems Corporation**
125 Blue Ball Rd
Elkton
Maryland
21921
USA

Date	Reference Number	Action
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
16 June 2022	3682750	Addition of subcontractor Isomedix Operations, Inc., 435 Whitney Street, Northborough, Massachusetts 01532 USA

Inspiring trust for a more resilient world.

16 June 2022

Terumo Cardiovascular Systems
Corporation
125 Blue Ball Rd
Elkton
Maryland
21921
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 584795	93/42/EEC Annex II excluding Section 4	3682750	Addition of subcontractor Isomedix Operations, Inc., 435 Whitney Street, Northborough, Massachusetts 01532 USA

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories.

Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Installation and serving of active medical devices.

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.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TERUMO EUROPE N.V. Interleuvenlaan 40 3001 Leuven Belgium	Design and development, manufacture and sterilization of syringes, needles, administration sets, angiographic interventional catheter systems, extra corporeal circuits for open heart surgery and ancillary devices, non-vascular guide wires, short peripheral catheters and related accessories. Clinical investigation, marketing and distribution of active and non-active medical devices, active implantable medical devices, and in vitro diagnostic medical devices. Installation and serving of active medical devices
/02	c/o Terumo Europe UK 3 Unity Grove Knowsley Business Park South Merseyside, Knowsley L34 9GT United Kingdom	Design and development, manufacture and sterilization of extra corporeal circuits for open heart surgery and ancillary devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/03	c/o Terumo Deutschland GmbH Ludwig-Erhard-Str. 6 65760 Eschborn Germany	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/04	c/o Terumo France S.A.S. Bâtiment Renaissance, 3 rond-point des Saules 78280 Guyancourt France	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/05	c/o Terumo Italia S.r.l. Via Paolo di Dono 73 00142 Roma Italy	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/06	c/o Terumo Europe España SL Avda. Juan Carlos I, N°13-7 Planta 28806 Alcalá de Henares (Madrid) Spain	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/07	c/o Terumo Europe UK Ltd. Otium House 2 Freemantle Road Bagshot Surrey GU19 5LL United Kingdom	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/08	c/o Terumo Europe N.V. Benelux Sales Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/09	c/o Terumo Sweden AB Sven Källfets gata 16 SE-426 71 Västra Frölunda Sweden	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/10	c/o Terumo Deutschland GmbH Zweigniederlassung Switzerland Bodenäckerstrasse 3 8957 Spreitenbach Switzerland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/11	c/o Terumo Europe N.V. European Distribution Center Brikkenovenstraat 48 3600 Genk Belgium	Storage and distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/12	c/o Terumo Europe N.V. Terumo Interventional Systems EMEA (TIS-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/13	c/o Terumo Europe N.V. Terumo Cardiovascular Europe Middle East & Africa (TCV-EMEA) Ludwig-Erhard-Straße 6 65760 Eschborn Germany	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/14	c/o Terumo Europe N.V. Terumo Medical Products EMEA (TMP-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/15	c/o Terumo Europe N.V. Diabetes Management EMEA (DM-EMEA) Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/16	c/o Terumo Europe N.V. Terumo Pharmaceutical Solutions Interleuvenlaan 40 3001 Leuven Belgium	Marketing of active and non-active medical devices and active implantable medical devices
/17	c/o Terumo Deutschland GmbH Zweigniederlassung Austria Liebermannstrasse F10-301 2345 Brunn am Gebirge Austria	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

D. Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1594584-1

Organization: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

The scope of certification also covers the following sites:

/18	c/o Terumo Europe N.V. Emerging Market Division Interleuvenlaan 40 3001 Leuven Belgium	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices
/19	c/o Terumo Poland Sp. Zoo Wisniowy Business Park budynek D ul. 1 Sierpnia 6 02-134 Warszawa Poland	Distribution of active and non-active medical devices, active implantable medical devices, and in-vitro diagnostic medical devices

Report No.: 3350367-50
Effective date: 2021-12-08
Expiry date: 2024-12-07
Issue date: 2021-11-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. (FH) D. Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60134707 0001

Report No.: 21240046 017

Manufacturer:
TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products: (see attachment for products and additional sites included)

Replaces Certificate, Registration No.: HD 60106290 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2020-04-21

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products included:

- Syringes
- Needles
- Administration sets
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Introducer for vascular access
- Angiographic Catheters
- Guidewire for Angiography

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:
- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134707 0001
Report No.: 21240046 017

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

additional sites included:

Terumo Europe N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Terumo Europe UK
3 Unity Grove, Knowsley Business Park South
Knowsley, Merseyside L34 9GT, United Kingdom

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Prüfzertifizierungsstelle

Date: 2020-04-21

Dipl.-Ing. (FH) D. Wiedemuth

Terumo Cardiovascular Group
125 Blue Ball Road, Elkton, Maryland 21921
Main: 410.398.8500
Toll-free: 800.283.7866
www.terumo-cvgroup.com

DECLARATION OF CONFORMITY

We, TERUMO CARDIOVASCULAR SYSTEMS CORPORATION, located at 125 Blue Ball Rd., Elkton, Maryland USA 21921, and being the manufacturer of:

Terumo® Capiox Oxygenators/Reservoirs

Product Codes: CX*SX18R, CX*SX18X, CX*SX18RX, CX*SX18R03, CX*SX25R, CX*SX25X, CX*SX25RX, 3CX*RX25RE, 3CX*RX25RW, 3CX*RX15RW30, 3CX*RX15RE30, 3CX*RX15RW40, 3CX*RX15RE40, 3CX*FX15RW30C, 3CX*FX15RW40C, 3CX*FX15RE30C, 3CX*FX15RE40C, 3CX*FX25REC, 3CX*FX25RWC, 3CX*R4000C

Classification: Class IIa – Rule 3 of Annex IX

Declare that the above products 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 the EC Council Directive 93/42/EEC Article 11, 2 and 3(a) relating to the "Full quality assurance" set out in Annex II, under the supervision of BSI (Certificate Registration No. CE 584795), as Notified Body authorized by the Netherlands Competent Authority and carrying the Notified Body No. 2797.

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

Adam Pickholtz
Regulatory Affairs Manager
Terumo Cardiovascular Systems Corp.
Elkton, Maryland 21921 USA

5/1/19
Date

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

TUBING SET with X-coating (optional)

Product: **Extra-Corporeal Blood Circuit for open heart surgery**
(See Appendix A for related product codes)

declare that the above product of Class IIa is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and has 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 System" set out in Annex II, and by certification of Annex II.3 (Registration No: HD 60106290 0001), 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.

Leuven, 21 December 2018
(place and date of issue)

M.J. Aerts
VP Regulatory & Quality
TERUMO EUROPE N.V.

Appendix A – Related product codes

The product code is composed of 10 digits maximum and explained as follows:

Customer requested device configurations

1	2	3	4	5	6	7	8	9	10
C	**X**	For Capiox® Cardiovascular Devices							
Manufacturer		**-**	Terumo Europe						
Coded countries of European sales branches/other sales blocks			**c**	**c**					
Sequential number					**n**	**n**	**n**	001, ...	
X-coating								**X**	Void if no X-coated component is included
Variant pack requested by customer								**A**	Sequential letter (A, B, ..., Z) – void if no variant pack

Standard device configurations

1	2	3	4	5	6	7	8	9	10
C	**X**	For Capiox® Cardiovascular Devices							
Manufacturer		**-**	Terumo Europe						
Standard Finished product			**F**						
Type of pack				**T**	**S**	Terumo Standard Pack			
Sequential number						**0**	**0**	**1**	
X-coating								**X**	X-coated components

Accessory packs for reduced prime circuits:

- Standard device configurations

1	2	3	4	5	6	7
C	X	For Capiox® Cardiovascular Devices				
Manufacturer		-	Terumo Europe			
Standard ROCsafe Accessory Pack		R	O	C		
Type of Accessory pack		A	with flexible venous resevoir			
		B	with hardshell venous reservoir and rigid adult sucker			
		C	with rigid adult sucker			
		G	Table Set			
		H	for pressure monitoring			

- Customer requested device configurations

1	2	3	4	5	6	7	8	9
C	X	For Capiox® Cardiovascular Devices						
Manufacturer		-	Terumo Europe					
Reduced prime optimised circuit		R	O	C				
Sequential letter					N	A, B, ...		
Sequential number						n	n	01, ...

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

Scope: Design and Development, Manufacture, Service and Sterilization (ETO, E-beam) of
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Haemoconcentration Filter
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Blood Reservoir
- Angiographic Catheter
- Stents
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Catheter Introducer
- Wire Twister
- Guiding Catheter
- Extension Tube
- Coronary Imaging Catheters
- Centrifugal Pump
- Radial Artery Hemostasis Band

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.: 12031333 010

Effective date: 2021-01-10

Expiry date: 2023-07-09

Issue date: 2020-12-23

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization:

Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

Design and Development, Manufacture, Service and Sterilization (ETO, E-beam) of
- Temperature Control Unit for Heart-Lung Bypass System Module
- Air/Fluid Level Detector for Heart-Lung Bypass System Module
- Centrifugal Pump Controller
- Syringe Infusion Pump
- Infusion Pump
- Clinical Electronic Thermometer
- Deep Body Temperature Monitor
- Clinical Electronic Blood-Pressure Meter
- Medical Equipment for Blood Collection
- Medical Equipment for APD Systems
- Sterile Tube Connecting Systems
- Coronary Optical Coherence Tomography Systems
- Blood Glucose Meters for Blood Glucose Monitoring Systems

Report No.: 12031333 010

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

Masahiro Asami
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	Terumo Corporation Ashitaka Plant 150, Maimaigi-cho Fujinomiya-shi Shizuoka, 418-0015 Japan	Activities related to Design and Development, Manufacture and Sterilization (ETO, E-beam) of the same as the scope of the main certificate except for design and development of Blood Glucose Meters for Blood Glucose Monitoring Systems.

Report No.: 12031333 010

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Akkreditierungsstelle
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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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Quality Management System
EN ISO 13485:2016

Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

/02	Terumo Corporation - Tokyo office 3-20-2 Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Activities related to service of all the active medical devices in the scope of the main certificate except for Blood Glucose Meters for Blood Glucose Monitoring Systems. Specifically, Temperature Control Unit for Heart-Lung Bypass System Module, Air/Fluid Level Detector for Heart-Lung Bypass System Module, Centrifugal Pump Controller, Syringe Infusion Pump, Infusion Pump, Clinical Electronic Thermometer, Deep Body Temperature Monitor, Clinical Electronic Blood-Pressure Meter, Medical Equipment for Blood Collection, Medical Equipment for APD Systems, Sterile Tube Connecting Systems, Coronary Optical Coherence Tomography Systems.

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Quality Management System
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Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

/03	Terumo Corporation, Shonan Center 1500 Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Activities related to Design and Development and Service of all the active medical devices in the scope of the main certificate except for Blood Glucose Meters for Blood Glucose Monitoring Systems.Specifically, Temperature Control Unit for Heart-Lung Bypass System Module, Air/Fluid Level Detector for Heart-Lung Bypass System Module, Centrifugal Pump Controller, Syringe Infusion Pump, Infusion Pump, Clinical Electronic Thermometer, Deep Body Temperature Monitor, Clinical Electronic Blood-Pressure Meter, Medical Equipment for Blood Collection, Medical Equipment for APD Systems, Sterile Tube Connecting Systems, Coronary Optical Coherence Tomography Systems.

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Registration No.: SX 1567993-1

Organization: Terumo Corporation
Ashitaka Plant
150, Maimaigi-cho
Fujinomiya-shi
Shizuoka,
418-0015 Japan

The scope of certification also covers the following:

/04	Terumo Corporation - ME Center (Nagaizumi) 1002-1 Shimonagakubo Nagaizumi-cho, Sunto-gun, Shizuoka 411-0934 Japan	Activities related to Design and Development, Manufacture and Service of all the active medical devices in the scope of the main certificate except for Blood Glucose Meters for Blood Glucose Monitoring Systems.Specifically, Temperature Control Unit for Heart-Lung Bypass System Module, Air/Fluid Level Detector for Heart-Lung Bypass System Module, Centrifugal Pump Controller, Syringe Infusion Pump, Infusion Pump, Clinical Electronic Thermometer, Deep Body Temperature Monitor, Clinical Electronic Blood-Pressure Meter, Medical Equipment for Blood Collection, Medical Equipment for APD Systems, Sterile Tube Connecting Systems, Coronary Optical Coherence Tomography Systems.

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