

DECLARATION OF CONFORMITY

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

being the manufacturer of:

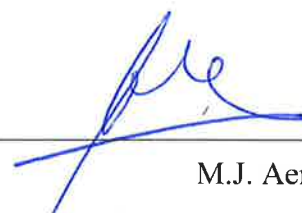
TUBING SET with X-coating (optional)

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 Capiiox® 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 Capiiox® Cardiovascular Devices						
Manufacturer		-	Terumo Europe					
Reduced prime optimised circuit		R	O	C				
Sequential letter					N	A, B, ...		
Sequential number					n	n	01, ...	