



Terumo Cardiovascular Group
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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

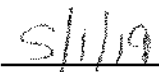
Classification: Class IIa – Rule 3 of Annex IX

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. CP 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.
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Date