

Declaration of Conformity

We, Terumo Cardiovascular Systems Corporation

6200 Jackson Road, Ann Arbor, MI 48103

Being the manufacturer of:

Product Names	Model Numbers
CDI™ System 500 Monitor with Arterial	500A
CDI™ System 500 Monitor with Art/Ven	500AV
CDI™ System 500 Monitor with Art/HS	500AHCT
CDI™ System 500 Monitor with Art/Ven/HS 500AVHCT	500AVHCT
Reconditioned, CDI™ System 500 Monitor with Arterial	500AR
Reconditioned, CDI™ System 500 Monitor with Art/Ven	500AVR
Reconditioned, CDI™ System 500 Monitor with Art/HS	500AHCTR
Reconditioned, CDI™ System 500 Monitor with Art/Ven/HS	500AVHCTR

Product Classification: Class IIb Rule 10 of Annex IX


Declare that the above products of Class IIb are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and have been subject to the conformity assessment procedure laid down in Article 11.3(a) relating to the "Full quality assurance" set out in Annex II, under the supervision of TUV Rheinland Product Safety GmbH, Am Grauen Stein, D-51105, Koln by certification of Annex II, Article 3 (Certificate registration No. HD 60016475 0001), as Notified Body authorized by the German competent Authority and carrying the Notified Body No. 0197.

Effective November 22, 2006

Authorized European Representative:

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

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(Place and date of issue)


Christina Thomas
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Terumo Cardiovascular Systems Corporation