

Declaration of Conformity

Manufacturer: AtCor Medical Pty Ltd
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 1059-1063 Victoria Road
 West Ryde, NSW
 Australia

European Representative: Advena Ltd
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 Hereford HR4 9DQ
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Notified Body: SGS United Kingdom Ltd
 Weston-Super-Mare
 Unit 202b, Worle Parkway
 Weston-Super-Mare, BS22 0WA
 United Kingdom



Product:	SphygmoCor Cardiovascular Management System (CvMS)
Description:	The SphygmoCor CvMS consists of the following modes: Central Pressure Analysis (PWA), Pulse Wave Velocity (PWV), Pulse Wave Monitoring (PWM) and Heart Rate Variability (HRV).
Standards Applied:	IEC EN 60601-1 IEC EN 60601-1-2 IEC EN 60601-1-4 IEC EN 62366 IEC EN 62304
Classification:	Class IIa Rule 10 of Annex IX
Conformity Assessment Route:	Annex II (excluding Section 4), 93/42/EEC
Products covered:	<i>Serial number of first system shipped under annex II</i>

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC, all prior amendments and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.



 John Abram
 Manager, Regulatory Affairs and Quality Assurance
 AtCor Medical Pty Ltd
 Sydney, NSW, Australia

17th March, 2010

 Date