



HeartSine®

Lifesaving technology designed for the real world



## EC Declaration of Conformity

Manufacturer: **HeartSine Technologies Limited**

Canberra House  
203 Airport Road West  
Belfast, BT3 9ED

Device: **samaritan PAD 300P**

Model: **SAM 300P**

Description: Automated external defibrillator.

Medical Device Classification: **IIb via Annex II (excluding Section 4) Full Quality Assurance System**

HeartSine Technologies declares that the HeartSine samaritan PAD 300P (SAM 300P), a therapeutic medical device in the range of Automated External Defibrillators, and its associated accessories are designed and manufactured:

- a) in conformity with the essential requirements and provisions of the European Medical Device Directive (MDD) **European Council Directive 93/42/EEC** (as amended by 2007/47/EC)
- b) under the supervision of SGS UK Ltd (Notified Body Number 0120)

**SGS UK Ltd,**  
Unit 202b Worle Parkway,  
Weston-super-Mare,  
United Kingdom, BS22 6WA

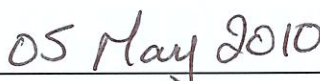
<b>Certification</b>	<b>SGS Certificate Number</b>
Council Directive 93/42/EEC	GB02/54193
ISO 13485:2003	GB02/54195
ISO 9001:2008	GB02/54194

Signature

  
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Dr Iffat Noor  
Director QA/RA  
HeartSine Technologies Ltd.

Date

  
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5<sup>th</sup> May 2010

H001-011-001-1