HeartSine
Inventor. Innovator. Lifesaver.

EC Declaration of Conformity

Manufacturer:HeartSine Technologies Limited
Canberra House
203 Airport Road West
Belfast, BT3 9ED

Device:	**samaritan PAD with CPR Advisor 500P**
Model:	**SAM 500P**
Description:	Automated external defibrillator.
Medical Device Classification:	Identified as **Class IIb** under rule 9 of Annex IX of Council Directive 93/42/EEC as amended by 2007/47/EC

HeartSine Technologies declares that the HeartSine samaritan PAD with CPR Advisor 500P (SAM 500P), a therapeutic medical device in the range of Automated External Defibrillators, and its associated accessories are designed and manufactured in conformity with:

- the essential requirements (Annex I) and provisions of the European Medical Device Directive (MDD) **European Council Directive 93/42/EEC** (as amended by 2007/47/EC)
  - And is subject to the procedure set out in Annex II (excluding section 4), Full Quality Assurance System, of Directive 93/42/EEC, as amended by Directive 2007/47/EC;
  - Under the supervision of notified body number CE0120, SGS United Kingdom Limited, Worle Parkway, Weston Super Mare, United Kingdom, BS22 6WA.

- Article 4 of ROHS2 Directive (2011/65 EU), with exceptions Annex III (6c – lead in copper alloy) and Annex IV (17 – lead in solder for portable emergency defibrillators).

Certification	SGS Certificate Number
Council Directive 93/42/EEC	GB02/54193
ISO 13485:2003	GB02/54195
EN ISO 13485:2012	GB02/54195
ISO 9001:2008	GB02/54194

Signature _____ Date 21 Jul 14

Paul Phillips
VP Quality & Regulatory Affairs
HeartSine Technologies Ltd.

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