



HeartSine®

Inventor. Innovator. Lifesaver.

EC Declaration of Conformity

Manufacturer: **HeartSine Technologies Limited**

Canberra House
203 Airport Road West
Belfast, BT3 9ED

Device: **samaritan PAD 350P**

Model: **SAM 350P**

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 350P (SAM 350P), 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) via Annex II (excluding Section 4) Full Quality Assurance System.
- b) under the supervision of SGS United Kingdom Ltd (Notified Body Number 0120)

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

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

James McGuinness
Quality Manager
HeartSine Technologies Ltd.

Date

16th Sept 2013.

H001-011-010-0