



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 500P

Description:

Semi-automatic external defibrillator with CPR advisor.

I hereby declare that the medical device, in the range of External Defibrillators, described hereafter as the samaritan PAD 500P is

a) in conformity with the essential requirements and provisions of the

Council Directive 93/42/EEC

b) subject to the procedure set out in Annex II of the Directive 93/42/EEC under the supervision of Notified Body Number 0120,

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

Signed

Lorcan McMahon

02 Feb 2010

Lorcan McMahon

02nd February 2010

Senior Quality Engineer
HeartSine Technologies Limited

The management system of

HeartSine Technologies Limited

Canberra House, 203 Airport Road West,
Belfast, BT3 9ED, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

Annex II (excluding Section 4)

For the following products

**Automatic External Defibrillators for adult and paediatric use.
Paediatric automated external defibrillator battery and defibrillation
electrode cartridges.**

This certificate is valid from 06 July 2007 until 06 January 2011 and
remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 18 January 2002

Notified Body Number 0120

Authorised by

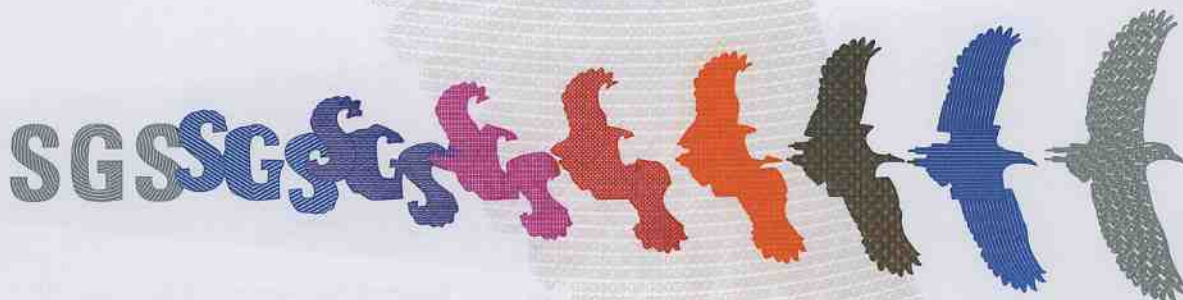
P. Earl

**CE
0120**

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0107

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SGS

Certificate GB02/54195

The management system of

HeartSine Technologies Limited

Canberra House, 203 Airport Road West,
Belfast, BT3 9ED, UK



has been assessed and certified as meeting the requirements of

ISO 13485:2003

For the following activities

**Design, manufacture, refurbish, repair, service and supply of
automatic external defibrillators and associated accessories**

This certificate is valid from 06 July 2010 until 06 July 2013 and
remains valid subject to satisfactory surveillance audits.

Re certification audit due before 06 July 2013

Issue 8. Certified since 18 January 2002

Authorised by

A handwritten signature in black ink, appearing to be "R. J. S.", is written over a faint background of the word "SGS" repeated in a grid.

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 1109

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Heartsine Technologies Ltd
Canberra House
203 Airport Road West
Belfast
Ireland
BT3 9ED

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Certificate of Test

Electrical Safety
For
Portable Defibrillator Unit

Date of Issue: 18th August 2006

SGS Reference: ELS 102384/1/C/RG/06

Details of Sample: Model : Samaritan Pad "SAMPAD" P/N - SAM 300
Serial No : 04-0001356

Date of Receipt: 17th July 2006

Date of Test: 20th July 2006 to 11th August 2006

Test Specification: Test for compliance with IP56 as described in BS EN 60529:1992 incorporating Amendments 1 & 2 (Degrees of protection provided by enclosures (IP code))

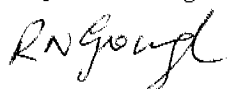
Conclusion: The sample tested was found to comply with IP5X (category 1) and IPX6. and therefore complies with IP56 as required by the standard.

This certificate is issued by the Company subject to its General Conditions of Service available upon request and accessible at www.sgs.com. Attention is drawn to the limitations of liability, indemnification, jurisdictional, representative restrictions of test samples and sample retention policies defined therein.

This certificate refers only to the sample submitted for test.

This certificate shall not be reproduced except in full without the written approval of SGS United Kingdom Ltd.

Authorised Signatory: R. N. Gough



Counter Signatory : S. Wilkinson



All enquires relating to this certificate must be directed to the Authorised Signatory

QUAL 08 Rev 5

Certificate GB02/54193

The management system of

HeartSine Technologies Limited

Canberra House, 203 Airport Road West,
Belfast, BT3 9ED, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

Annex II (excluding Section 4)

For the following products

**Automatic External Defibrillators for adult and paediatric use.
Paediatric automated external defibrillator battery and defibrillation
electrode cartridges.**

This certificate is valid from 06 July 2010 until 06 July 2013 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 06 July 2013
Issue 7. Certified since 18 January 2002

Notified Body Number 0120

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
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SGS CE 01 0308

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HeartSine

EC DECLARATION of CONFORMITY

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

Declares that the medical device, in the range of External Defibrillators,
described hereafter as

The HeartSine PDU class IIb medical device, model PDU 400 is in conformity
with the essential requirements and provisions of the Council Directive
93/42/EEC

and

is subject to the procedure set out in Annex II of the Directive 93/42/EEC under
the supervision of Notified Body Number 0120, SGS UK Ltd, Unit 202b Worle
Parkway, Weston-super-Mare, United Kingdom, BS22 6WA.

Belfast, 25th February 2008

Prof John Anderson
(Chief Technical Officer)



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

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

Signature

Date

Dr Iffat Noor
Director QA/RA
HeartSine Technologies Ltd.

5th May 2010

H001-011-001-1