HeartSine
Inventor. Innovator. Lifesaver.

EC Declaration of Conformity

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

Device: **HeartSine PDU 400**
Model: **PDU 400**
Description: Automated External Defibrillator
Medical Device Classification: **Class IIb**
(European Council Directive 93/42/EEC, Annex 9; Rule 9).

HeartSine Technologies declares that the HeartSine PDU 400 (PDU 400), a therapeutic medical device in the range of Automated External Defibrillators, are designed and manufactured:

a) in conformity with the essential requirements and provisions of the European Medical Device Directive **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)

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 9001:2000	GB02/54194

Signature _____ Date 16th Sept 2013.

James McGuinness
Quality Manager
HeartSine Technologies Ltd.

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