



HeartSine®

Inventor. Innovator. Lifesaver.

EC Declaration of Conformity

Manufacturer: **HeartSine Technologies Limited**

Canberra House
203 Airport Road West
Belfast
BT3 9ED

Device: **PAD-Pak**

Model: **PAD-PAK-03**

Description: **Combined Battery and Electrode Cartridge**

Medical Device Classification: **Class I via EC Declaration of Conformity**

HeartSine Technologies declares that the HeartSine PAD-Pak (PAD-PAK-03), an accessory to a therapeutic medical device in the range of Automated External Defibrillators, are designed and manufactured 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)

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

16th Sept 2013

James McGuinness
Quality Manager
HeartSine Technologies Ltd.

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