

EC Declaration of Conformity

Manufacturer:

HeartSine Technologies Limited

Canberra House 203 Airport Road West Belfast, BT3 9ED

UK

Device:

samaritan® PAD 360P

Model:

SAM 360P

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 360P (SAM 360P), a therapeutic medical device in the range of Automated External Defibrillators, and its associated accessories are designed and manufactured in conformity with:

- a) 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)
 - o 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

ISO 13485:2003

EN ISO 13485:2012

ISO 9001:2008

GB02/54193

GB02/54195

GB02/54195

GB02/54194

Signature

Date 23RD FEB 2016.

James McGuinness

Quality Manager

HeartSine Technologies Ltd.