

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

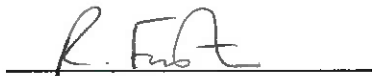
HeartSine Technologies declares that the HeartSine samaritan PAD 360P (SAM 360P), a therapeutic medical device in the range of Automated External Defibrillators, and its associated accessories are designed and manufactured in conformity with:

- 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)
 - 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 CE0123, **TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany.**
- 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
Council Directive 93/42/EEC
ISO 13485:2016
EN ISO 13485:2016

TÜV Certificate Number
No. G1 067590 0002 Rev. 00
No. Q5 067590 0001 Rev. 00
No. Q5 067590 0001 Rev. 00

Signature



Date

15 April 2019

Rebecca Funston

Senior Manager, Regulatory Affairs & Quality Assurance
HeartSine Technologies Ltd.