HeartSine

EC Declaration of Conformity

Manufacturer:	**HeartSine Technologies Limited** Canberra House 203 Airport Road West Belfast, BT3 9ED UK
Device:	**samaritan PAD with CPR Advisor 500P**
Model:	**SAM 500P**
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 with CPR Advisor 500P (SAM 500P), a therapeutic medical device in the range of Automated External Defibrillators, and its associated accessories are designed and manufactured in conformity with:

- 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	***TÜV* Certificate Number**
Council Directive 93/42/EEC	***No. G1 067590 0002 Rev. 00***
ISO 13485:2016	***No. Q5 067590 0001 Rev. 00***
EN ISO 13485:2016	***No. Q5 067590 0001 Rev. 00***

Signature R. Funston Date 15 April 2019

Rebecca Funston

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