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

Scope of Declaration for Australia: Refer to Appendix 2.

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, Ridlerstraβe 65, 80339 Munich, Germany.
- Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.
    - Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.
    - It is subject to the Australian Standards Applied referred within Appendix 3.

- ROHS Directive (2011/65/EU), amended by RoHS3 Directive (EU 2015/863), with exemptions Annex IV number 17 lead solder in portable defibrillators, Annex III exemption 6c – copper alloy containing up to 4% lead by weight, exemption 7(a) – lead in high melting solders, exemption 7 (c)-I - Electrical and electronic components containing lead in glass or ceramics.

- HeartSine Technologies European Authorised Representative address is as follows; Stryker European Operations Limited, Anngrove, IDA Business & Technology Park, Carrigtwohill, Co Cork, T45HX08, Ireland.

HeartSine Technologies is exclusively responsible for this declaration of conformity.

Certification	TÜV Certificate Number
Council Directive 93/42/EEC	No. G1 067590 0006 Rev. 00
EN ISO 13485:2016	No. Q5 067590 0003 Rev. 00

Signature _____ *Electronically signed by: Rebecca Funston*
Reason: I approve this document
Date: Jun 25, 2020 12:12 GMT+1

Date 25-Jun-2020

Rebecca Funston

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

HeartSine

Appendix 1

Ref	Description	GMDN Code
500-STR-CA-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-CZ-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-DA-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-DE-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-EL-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-ES-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-FI-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-FR-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-HR-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-HU-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-IS-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-IT-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-NL-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-NO-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-PO-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-PT-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-RO-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-SL-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-SV-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-TR-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-UK-10	1 SAM 500P with 1 Adult Pad-Pak	47910
500-STR-CA-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-CZ-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-DA-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-DE-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-EL-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-ES-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-FI-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-FR-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-HR-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-HU-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-IS-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-IT-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-NL-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-NO-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-PO-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-PT-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-RO-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-SL-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-SV-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-TR-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910
500-STR-UK-AV	1 SAM 500P with 1 Aviation Pad-Pak	47910

Appendix 2

Model

Item Number	Description	AU GMDN Code
500-BAS-UK-10	SAM 500P 1 Pad-Pak-03 UK English	37805
500-TSO-UK-10	SAM 500P 1 Pad-Pak-07 UK English	37805
500-BAS-USROW-10	SAM 500P 1 Pad-Pak-03 US English	37805
500-TSO-USROW-10	SAM 500P 1 Pad-Pak-07 US English	37805
500-BAS-UK-GW	PACKAGE, 500P, GATEWAY	37805
500-BAS-UR-GW	PACKAGE, 500P, GATEWAY	37805
500-STR-UK-10	***SAM 500P, Pad-Pak-03, UK English***	***37805***
500-STR-UK-AV	***SAM 500P, Pad-Pak-07, UK English***	***37805***

Appendix 3

Standards	Title
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
AAMI MDS	Developing safe, effective and reliable medical software
ANSI/AAMI EC57	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
EN 1041	Requirements for information supplied by medical device manufacturers
ISO 60529	Degrees of protection provided by enclosures (IP Code)
ISO 15223	Symbols to be used with medical device labels, labelling and information to be supplied
ISO 14971	Application of risk management to medical devices
ISO 10993	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
IEC 60878	Graphical Symbols for Electrical Equipment in Medical Practice
21 CFR 820	Quality System Regulation
EN 60601-1	General requirements for safety for medical electrical equipment
EN 60601-1-2	EMC requirements for medical electrical equipment
EN 60601-1-6	Safety requirements for usability
EN 60601-2-4	Safety requirements for cardiac defibrillators