EC Declaration of Conformity

Manufacturer:	**HeartSine Technologies Limited** Canberra House 203 Airport Road West Belfast BT3 9ED UK
Device:	Pediatric-Pak
Model:	PAD-PAK-02 & PAD-PAK-04
Description:	Combined Battery and Electrode Cartridge
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
Medical Device(s):	Refer to Appendix 1
Australian GMDN Code and Term:	47912; Non-rechargeable external defibrillator electrode, adult

HeartSine Technologies declares that the HeartSine Pediatric-Pak (PAD-PAK-02 & PAD-PAK-04), an accessory to a therapeutic medical device in the range of Automated External Defibrillators, are designed and manufactured:

a) 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)

b) 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;

c) 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.

d) Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.
   a. Each kind of medical device to which the technical documentation applied complies with the applicable provisions of the essential principles and classification rules before being supplied.
   b. It is subject to the Australian Standards Applied referred within Appendix 2.

e) Under the supervision of TÜV SÜD Product Service GmbH, (Notified Body Number 0123) TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraβe 65, 80339, Munich, Germany.

f) 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 000***3*** 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.

Appendix 1

Catalogue Number	Description
Pad-Pak-04	BATTERY, PAD-PAK-04 - Pediatric
Pad-Pak-02	***BATTERY, PAD-PAK-02 - Pediatric***

Appendix 2

Standard Reference	Standard Title
ISO 13485	Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
IEC 60601-1	Medical electrical equipment Part 1: General Requirements for basic safety and essential performance.
EN 60601-2-4	Medical electrical equipment Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601-2-4)
EN 55011	Industrial, scientific and medical equipment. Radio frequency disturbance characteristics.
BSEN 62304	Medical Device Software – Software lifecycle processes.
AAMI MDS	Developing safe, effective, and reliable medical software.
ANSI/AAMI EC57	Testing and reporting performance results of cardiac rhythm and STsegment measurement algorithms.
EN1041	Information supplied by the manufacturer of medical devices.
IEC 60529	Degrees of protection provided by enclosures (IP Code).
ANSI/AAMI/ISO 15223	Medical devices— Symbols to be used with medical device labels, labelling, and information to be supplied.
IEC 60878	Graphical symbols for electrical equipment in medical practice
AAMI TIR 24	Acquisition and use of physiologic waveform databases for testing of medical devices.
EN 62366-1	Medical devices Part 1: Application of usability engineering to medical devices.
EN 60601-1-6	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability
ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.
ISO 10993-5	***Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity***
ISO 10993-10	***Biological Evaluation of Medical Devices - Part 10: Tests for irritation and delayed hypersensitivity***

U.S./Americas 121 Friends Lane, Suite 400, Newtown, PA 18940 • P: 215.860.8100 • F: 215.860.8192
EMEA/ASP 203 Airport Road West, Belfast, Northern Ireland BT3 9ED • P: +44 (0) 28 90 93 94 00 • F: +44 (0) 28 90 93 94 01
www.heartsine.com