EC Declaration of Conformity

Manufacturer:	**HeartSine Technologies Limited** 207 Airport Road West Belfast, Northern Ireland BT3 9ED United Kingdom
Device:	**Pad-Pak**
Model:	**Pad-Pak-01 & Pad-Pak-03**
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, and in accordance with the Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 2
Medical Device(s):	Refer to Appendix 1

Scope of Declaration for Australia: **PADPAK03** – Combined Battery and Electrode Cartridge -Adult
Australian GMDN Code and Term: Refer to Appendix 2

HeartSine Technologies declares that the HeartSine Pad-Pak (PAD-PAK-01 & PAD-PAK-03), an accessory to a therapeutic medical device in the range of Automated External Defibrillators, 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 TÜV SÜD Product Service GmbH, (Notified Body Number 0123), TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraβe 65, 80339 Munich, Germany.

b) 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, the 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.

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) 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. 01
EN ISO 13485 : 2016	No. Q5 067590 0008 Rev. 00

Signature _____ Date _____

Electronically signed by:
Rebecca Funston
Reason: I approve
Date: Jun 21, 2021 17:42 GMT+1

Rebecca Funston

Director, Global Regulatory & Clinical Affairs
HeartSine Technologies Ltd.

Appendix 1

Catalogue Number	Description	GMDN Code
Pad-Pak-01	Non-rechargeable public semi-automated external defibrillator electrode, adult	47911
Pad-Pak-03	Non-rechargeable public semi-automated external defibrillator electrode, adult	47911

Appendix 2

Catalogue Number	Description	AU GMDN Code
Pad-Pak-03	Non-rechargeable external defibrillator electrode, Adult	47911

Appendix 3

Standard Reference	Standard Title
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 1041	Requirements for information supplied by medical device manufacturers
EN 60601-1	General requirements for safety for medical electrical equipment
EN 60601-1-6	Safety requirements for usability
IEC 60601-2-25	Medical electrical equipment - Part2-25: Particular requirements for the safety of electrocardiographs
IEC 60601-2-27	Medical electrical equipment - Part2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
ISO 14971	Application of risk management to medical devices
ISO 10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
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
ISO 14155	Clinical Investigation of medical devices for human subjects - Good Clinical Practice