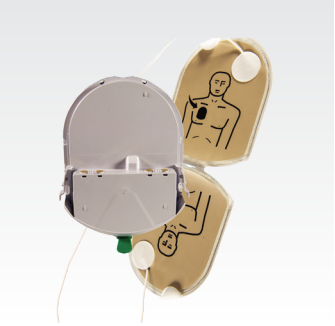
UK Master Distributor for

EC Declaration of Conformity



Adult Pad-Pak
For patients > 8 years or 25 kg (55 lb).

Manufacturer:	HeartSine Technologies Limited 207 Airport Road West Belfast, Northern Ireland BT3 9ED United Kingdom
Device:	**Pad-Pak**
Model:	**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

HeartSine Technologies declares that the HeartSine Pad-Pak (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) 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 is exclusively responsible for this declaration of conformity.

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Certification	TÜV Certificate Number
Council Directive 93/42/EEC	No. G1 067590 0006 Rev. 01
EN ISO 13485 : 2016	No. Q5 067590 0008 Rev. 01

Signature Anna Fabisch Fors Electronically signed by: Anna Fabisch Fors Reason: I approve this document Date: Mar 13, 2023 10:53 GMT+1 Date 2023-03-13

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

Appendix 1

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

Appendix 2

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