

EC Declaration of Conformity

Manufacturer: HeartSine Technologies Limited
Canberra House
203 Airport Road West
Belfast
BT3 9ED
UK

Device: Pad-Pak
Model: Pad-Pak-01 & Pad-Pak-03
Description: Combined Battery and Electrode Cartridge
Medical Device Classification: Class IIb under the provisions of the directive 93/42/EEC Rule 9 of Annex IX.
Scope of Declaration for Australia: PADPAK03 – Battery, PAD-PAK-03
Australian GMDN Code and Term: 47911; Non-rechargeable external defibrillator electrode, adult

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 is subject to the procedure set out in Annex II (excluding section 4) Full Quality Assurance System, of Directive provisions of the European Medical Device Directive (MDD) European Council Directive 93/42/EEC (as amended by 2007/47/EC)
- 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.
- c) 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 1.
- d) Under the supervision of TÜV SÜD Product Service GmbH, (Notified Body Number 0123)
TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339, Munich, Germany.
- e) 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.

