Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 067590 0002 Rev. 00

Manufacturer: **HeartSine Technologies, Ltd.**
Canberra House
203 Airport Road West
Belfast, BT3 9ED
UNITED KINGDOM

Product Category(ies): Automatic External Defibrillators for adult and paediatric use. Paediatric automated external defibrillator battery and defibrillator electrode cartridges:

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 75944443

Valid from: 2019-03-30
Valid until: 2021-07-06

Date, 2019-03-29

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

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(Devices in Class IIa, IIb or III)

No. G1 067590 0002 Rev. 00

Facility(ies):

HeartSine Technologies, Ltd.
Canberra House , 203 Airport Road West, Belfast, BT3 9ED, UNITED KINGDOM

Heartsine Technologies Limited
2 Heron Road, Belfast, BT3 9LE, UNITED KINGDOM

Heartsine Technologies Limited
207 Airport Road West, Belfast, BT3 9LF, UNITED KINGDOM

Heartsine Technologies Limited
Unit 6, Site 31 Sydenham Business Park, Heron Avenue, Belfast, BT3 9LF, UNITED KINGDOM

Heartsine Technologies Limited
4 Heron Road, Belfast, BT3 9LE, UNITED KINGDOM

Heartsine Technologies Limited
Unit 3-5, Site 31 Sydenham Business Park, Heron Avenue, Belfast, BT3 9LF, UNITED KINGDOM

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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