

Certificate GB02/54195

The management system of

HeartSine Technologies Limited

Canberra House, 203 Airport Road West, Belfast, BT3 9ED, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 05 September 2018 until 06 July 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 06 July 2019

Issue 14. Certified since 18 January 2002

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



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SGS United Kingdom Ltd
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HC SGS 13485 2016 0118 M2

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HeartSine Technologies Limited

ISO 13485:2016
EN ISO 13485:2016



Issue 14

Detailed scope

Design, manufacture and distribution of automatic external defibrillators and defibrillator battery and defibrillation PADS cartridges.

Additional facilities

2 Heron Road, Belfast, BT3 9LE, UK

4 Heron Road, Belfast, BT3 9LE, UK

Unit 6, Site 31 Sydenham Business Park, Heron Avenue, Belfast, BT3 9LF, UK

Unit 3-5, Site 31 Sydenham Business Park, Heron Avenue, Belfast, BT3 9LF, UK

207 Airport Road West, Belfast, BT3 9LF, UK



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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2013

Heartsine Technologies Inc.
c/o Mr. James McGuinness
Quality Manager
Canberra House
203 Airport Road West
Belfast, BT3 9ED
Northern Ireland

Re: K123881

Trade/Device Name: Samaritan PAD 350P AED
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: June 18, 2013
Received: June 19, 2013

Dear Mr. McGuinness:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Page 2 – Mr. James McGuinness

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Owen P. Faris -S

for
Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123881

Section <b style="font-size: 2em;">4	<h1 style="margin: 0;">Indications for Use</h1>
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510(k) Number (if known): _____

Device Name: HeartSine Technologies, Ltd. samaritan® PAD 350P

The HeartSine samaritan® PAD 350P (also known as PAD 350P and SAM 350P) is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The samaritan® PAD 350P is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program.

The samaritan® PAD 350P is indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult samaritan® Pad-Pak (Pad-Pak-01 or Pad-Pak-07).

The samaritan® PAD 350P is indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the samaritan® Pediatric-Pak (Pad-Pak-02).

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Owen P. Faris -S
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Prescription Use: or Over-the-Counter Use: