HeartSine

EU Declaration of Conformity TO MEDICAL DEVICE REGULATION 2017/745	
Manufacturer Name	HeartSine Technologies Limited
Manufacturer SRN	XI-MF-000004230
Manufacturer Address	207 Airport Road West Belfast, Northern Ireland, BT3 9ED United Kingdom
See Appendix 1 for Device information	
We hereby declare under our sole responsibility that these products conform with the relevant provisions of the Medical Device Regulation 2017/745. Each of the listed and CE-marked products in the appendix has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the Medical Device Regulations 2017/745 prior to being placed on the market. This Declaration of Conformity is valid in conjunction with the respective production release records for the referenced devices. This declaration applies to CE Marked devices produced after the date issuance of this declaration and before it is superseded be another declaration or withdrawn.	
We declare, under our sole responsibility, that the products specified in the product list also conform to the following regulations and directives.	2015/863 RoHS 3 Directive

Name and ID # of Notified Body	Description of Conformity Assessment Procedure	Issued Certificate Number
TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraβe 65, 80339 Munich, Germany 0123	Annex IX, Chapter I, II and III, Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation	G12 067590 0010 Rev. 00 G70 067590 0011 Rev. 00

Reference to Common Specifications (Write N/A when not applicable)	N/A There are no Common Specifications available at signing of this DoC relating to the samaritan PAD devices.
Additional Information (Write N/A when not applicable)	N/A
Name of Responsible Person or Designee	Karen Lockhart
Function of Responsible Person or Designee	Associate Manager, Regulatory Affairs
Place of Issue	Belfast, Northern Ireland, UK
Date of Issue	29 December 2023
Signature	Electronically signed by: Karen Lockhart Reason: I approve this document Date: Dec 6, 2023 14:17 GMT

Appendix 1 – Products covered by Declaration of Conformity

AAA-BBB-XX-YY (where AAA is the device model e.g., 350/360/500/550, BBB is the shipping variant e.g., STR/BAS, XX is the assigned language e.g., FR=French and YY the packing variant e.g., 10=supplied with adult Pad-Pak, AV=supplied with Aviation Pad-Pak and GW =supplied with a Gateway and an adult Pad-Pak).

Product and Accessories Trade Name	Product Number	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	GMDN Code	CND/EMDN code	MDA Code	CE TD Number	Initial CE release date
HeartSine samaritan PAD 500P (SAM 500P)	500-STR-XX-YY 500-BAS-XX-YY 500-TSO-XX-YY	08858 25100 2132S 4	Class III	Rule 22	The HeartSine samaritan PAD family of AEDs is designed to automatically assess the patient's heart rhythm and advise and/or automatically deliver a defibrillation shock to victims of sudden cardiac arrest if required. The use of a samaritan PAD defibrillator, to deliver the therapeutic electric shock across the heart can stop the disruption to the heart's normal rhythm and restore blood-flow.	47910	Z12030501	MDA 0305	M0000002606	February 2010
HeartSine samaritan PAD 350P (SAM 350P)	350-STR-XX-YY 350-BAS-XX-YY 350-TSO-XX-YY	08858 25100 2132S 4	Class III	Rule 22	The HeartSine samaritan PAD family of AEDs is designed to automatically assess the patient's heart rhythm and advise and/or automatically deliver a defibrillation shock to victims of sudden cardiac arrest if required. The use of a samaritan PAD defibrillator, to deliver the therapeutic electric shock across the heart can stop the disruption to the heart's normal rhythm and restore blood-flow.	47910	Z12030501	MDA 0305	M0000002606	February 2013
HeartSine samaritan PAD 360P (SAM 360P)	360-STR-XX-YY 360-BAS-XX-YY 360-TSO-XX-YY	08858 25100 2132S 4	Class III	Rule 22	The HeartSine samaritan PAD family of AEDs is designed to automatically assess the patient's heart rhythm and advise and/or automatically deliver a defibrillation shock to victims of sudden cardiac arrest if required. The	48047	Z12030503	MDA 0305	M0000002606	August 2014

					use of a samaritan PAD defibrillator, to deliver the therapeutic electric shock across the heart can stop the disruption to the heart's normal rhythm and restore blood-flow.					
HeartSine samaritan PAD 550P (SAM 550P)	550-STR-XX-YY	08858 25100 2132S 4	Class III	Rule 22	The HeartSine samaritan PAD family of AEDs is designed to automatically assess the patient's heart rhythm and advise and/or automatically deliver a defibrillation shock to victims of sudden cardiac arrest if required. The use of a samaritan PAD defibrillator, to deliver the therapeutic electric shock across the heart can stop the disruption to the heart's normal rhythm and restore blood-flow.	47910	Z12030501	MDA 0305	M0000002606	TBC

M0000002609-AB SAM PAD Combined Declaration of Conformity

Final Audit Report 2023-12-06

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"M0000002609-AB SAM PAD Combined Declaration of Conformity" History

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