

## EC Declaration of Conformity

**Manufacturer:** HeartSine Technologies Limited

207 Airport Road West  
Belfast, BT3 9ED  
Northern Ireland  
United Kingdom

**Device:** HeartSine samaritan® PAD 500P Trainer

**Model:** TRN-500-1

**Description:** Trainer device for samaritan® PAD 500P

HeartSine Technologies declares that the HeartSine samaritan® PAD 500P Trainer (TRN-500-1), are designed and manufactured in conformity with

- a) EN 61000 Part 6-3: 2007+A1:2011 Electromagnetic Compatibility (EMC) Generic standards – Emission standards for residential, commercial and light industrial environments.
- b) EN 61000 Part 3-2: 2014 Limits for harmonic current emissions
- c) EN 61000 Part 3-3: 2013 Limitations of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rate current  $\leq 16A$  per phase and not subject to conditional connection.
- d) EN 61000 Part 6-1: 2007 Electromagnetic Compatibility (EMC) Generic Standard – Immunity for residential, commercial and light industrial environments.
- e) Directive 2014/53/EU: Radio Equipment Directive (RED)

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.

**Certification**

Council Directive 93/42/EEC  
EN ISO 13485 : 2016

**TÜV Certificate Number**

No. G1 067590 0006 Rev. 01  
No. Q5 067590 0008 Rev. 00

Signature



Electronically signed by:  
Rebecca Funston  
Reason: I approve  
Date: Apr 21, 2021 13:05 GMT+1

Date

21-Apr-2021

**Rebecca Funston**

**Director, Global Regulatory & Clinical Affairs  
HeartSine Technologies Ltd.**