

EC Declaration of Conformity

Manufacturer: HeartSine Technologies Limited

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

Device: HeartSine samaritan® PAD 350P Trainer

Model: TRN-350-1

Description: Trainer device for samaritan® PAD 350P

HeartSine Technologies declares that the HeartSine samaritan® PAD 350P Trainer (TRN-350-1), 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.**