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1. Purpose

- 1.1. The purpose of this document is to provide all critical details of the *Trainer Declaration of Conformity Summary, H001-011-032* supplied by *any approved printed material supplier*. This document will include Details of *Trainer Declaration of Conformity Summary, H001-011-032*, Bill of Materials, Drawings of components, Specifications, Shipping & Handling Requirements, Goods in Acceptance Criteria, Certificate of Conformance, where applicable.

2. Scope

- 2.1. This document applies to component *H001-011-032* supplied by *any approved printed material supplier*.

3. Roles and responsibilities

- 3.1. HeartSine shall populate this template to ensure all critical information is documented.
- 3.2. The approved printed material supplier shall review the *Trainer Declaration of Conformity Summary*, to ensure content is correct.

4. Bill of Materials

- 4.1. This section shall provide a list of raw materials or each individual component and the quantities of each needed to manufacture the final product.

N/A as applicable

5. Drawing of components

- 5.1. This section shall provide design specifications and a schematic drawing and/or product images that visually illustrate the product and its individual components. This drawing should include clear labels, noting distinguishing characteristics.

Refer to Appendix A

6. Specifications

- 6.1. This section shall provide Stryker specifications detailing critical defining information about the product and components. Design specifications should be included where appropriate. This section shall define temperature and environmental conditions for manufacture.

SPECIFICATION	Finished Size	140mm x 140mm (+/-2mm)
	Flat Size	420mm x 140mm (+/-2mm)
	Page Count	2 Pages (Front and Back) including 6 Panels
	Print Method	Offset Lithograph or Digital Print.
	Colour Ref	Black
	Stock	80gsm Bond
	Binding	N/A
	Work Flow	Prepress, Print, Trim, Roll Fold, Pack, Label

PREPRESS	Print Ref on Artwork	Refer to Artwork
	Artwork Submission	Approved PDF supplied by E-mail
	Proofing Requirement	Pre-flight Artwork. Issue Ripped Printers Proof

PACKING	Packing	Standard CoC
	Non-Kits	Pack in Corrugated boxes. Labelling to include Part No/ Description/ QTY in box/ Batch (HeartSine Label) Weight restriction: <10kgs Standard or Euro pallet acceptable. Height restriction on Pallet: <200cms Mixed product ok on Pallet. But ensure each box is labelled

NOTES	File Naming	When artwork is updated the ending sequence of the filename will be updated
	Sampling	Production Sampling: Print Production: First and Last of batch of print run. Finished Product: First and Last of batch run.

7. Shipping, Handling and Packaging Requirements

7.1. This section shall detail shipping and handling requirements of the *Trainer Declaration of Conformity Summary, H001-011-032*, to ensure safety and quality of product. Shipping of dangerous goods require appropriate documentation, labels and must include MSDS information. This section shall also include packaging information, box type, box weight, quantity of units per box.

Requirements					
Part No.	Shipping	Handling	Packaging	Quantity units per box	Reusable Container
H001-011-032	Supplier Courier	Less than 10kgs per shipper box	Packed in labelled corrugated boxes	As agreed with supplier	N/A

8. Test Plan

8.1. This section shall state whether test plans or test specifications are required for the *Trainer Declaration of Conformity Summary, H001-011-032*. These may be provided to the supplier by HeartSine or may be developed between HeartSine and *any approved printed material supplier*. This section shall detail agreed test plans or test specifications.

N/A as applicable

9. Certificate of Conformance

A certificate of conformance certifies the *Trainer Declaration of Conformity Summary, H001-011-032* received from *any approved printed material supplier* are tested to

specifications defined by HeartSine. HeartSine requires a certificate of conformance from all critical component suppliers.

N/A as applicable

10. Goods In Inspection and Acceptance Criteria

This section shall detail the level of inspection required by HeartSine Goods in team and the acceptance criteria for incoming product(s).

Part Number	Part Description
H001-003-075	Appendix 1 to the Goods Inwards and Stores Procedure
H006-004-271	Manual Goods In Work Instruction

11. Appendices

- 11.1. Appendix A, *Trainer Declaration of Conformity Summary, H001-011-032*

Appendix A

Trainer Declaration of Conformity Summary, H001-011-032



HeartSine® samaritan® PAD Trainer Compliance with Directive 2014/53/EU

EN: Hereby, HeartSine Technologies, Ltd. declares that the HeartSine samaritan PAD Trainer* is in compliance with Directive 2014/53/EU.

- Frequency bands: 2412-2472 megahertz (MHz)
- Radio frequency power: No greater than 20 dbm

AB: بموجب هذا البيان، تعلن شركة HeartSine Technologies, Ltd. أن HeartSine samaritan PAD Trainer* يتوافق مع التوجيه الأوروبي 2014/53/EU.

- نطاقات التردد: ٢٤١٢-٢٤٧٢ ميجا هرتز
- قوة التردد اللاسلكي: لا تزيد عن ٢٠ ديسيبل مللي واط

ES-LA: Por este medio, HeartSine Technologies, Ltd. declara que el dispositivo HeartSine samaritan PAD Trainer* cumple satisfactoriamente con la directiva 2014/53/UE de la Union Europea.

- Bandas de frecuencia: 2412-2472 megahercios (MHz)
- Potencia de radiofrecuencia: Inferior a los 20 decibelios-milivattios

PT-BZ: A HeartSine Technologies, Ltd. declara por meio deste que o HeartSine samaritan PAD Trainer* está em conformidade com a Diretiva 2014/53/UE.

- Faixas de frequência: 2412-2472 mega-hertz (MHz)
- Potência de radiofrequência: não superior a 20 dbm

CA: Per la present, HeartSine Technologies, Ltd. declara que el HeartSine samaritan PAD Trainer* compleix la Directiva 2014/53/UE.

- Bandes de freqüència: 2412-2472 megahertz (MHz)
- Potència de radiofreqüència: 20 dbm màxim

CS: Společnost HeartSine Technologies, Ltd. tímto prohlašuje, že HeartSine samaritan PAD Trainer* je v souladu se směrnicí 2014/53/EU.

- Kmitočtová pásma 2412–2472 megahertz (MHz)
- Vysokofrekvenční výkon: ne vyšší než 20 dbm

DA: HeartSine Technologies, Ltd. erklærer hermed, at HeartSine samaritan PAD Trainer* overholder Direktive 2014/53/EU.

- Frekvensbånd: 2412-2472 megahertz (MHz)
- Radiofrekvensstyrke: Ikke større end 20 dbm

DE: Hiermit erklärt HeartSine Technologies, Ltd., dass das HeartSine samaritan PAD Trainer* die Richtlinie 2014/53/EU erfüllt.

- Frequenzbänder: 2412-2472 Megahertz (MHz)
- Hochfrequenzleistung: Max. 20 dbm

ET: Käesolevaga deklareerib ettevõte HeartSine Technologies, Ltd., et treeningseade HeartSine samaritan PAD Trainer* on vastavuses direktiiviga 2014/53/EL.

- Sagedusalad: 2412–2472 megahertsi (MHz)
- Raadiosagedusvõimsus: mitte suurem kui 20 dBm

EL: Με την παρούσα, η HeartSine Technologies, Ltd. δηλώνει ότι το HeartSine samaritan PAD Trainer* συμμορφώνεται με την Οδηγία 2014/53/ΕΕ.

- Ζώνες συχνοτήτων: 2412-2472 megahertz (MHz)
- Ισχύς ραδιοσυχνότητας: Όχι μεγαλύτερη από 20 dbm

ES-ES: Por la presente, HeartSine Technologies, Ltd. declara que HeartSine samaritan PAD Trainer* cumple la Directiva 2014/53/EU.

- Bandas de frecuencia: 2412-2472 megahercios (MHz)
- Potencia de radiofrecuencia: No superior a 20 dbm

FI: HeartSine Technologies, Ltd. ilmoittaa täten, että HeartSine samaritan PAD Trainer* on direktiivin 2014/53/EU vaatimusten mukainen.

- Taajuuskaistat: 2 412–2 472 megahertsiä (MHz)
- Radiotaajuusteho: enintään 20 dbm

FR: HeartSine Technologies, Ltd. déclare par la présente que le HeartSine samaritan PAD Trainer* est conforme à la directive 2014/53/UE.

- Bandes de fréquence : 2412-2472 mégahertz (MHz)
- Puissance de radiofréquence: Inférieure ou égale à 20 dBm

HE: HeartSine Technologies Ltd. מצהירה בזאת כי HeartSine samaritan PAD Trainer* עומדת בתקנים 2014/53/EU.
• להקות תדרים: 2412 עד 2472 מגה-הרץ (MHz)
• עוצמת תדר רדיו: לא יותר מ-20 dbm

HI: एतद्दवारा, HeartSine Technologies, Ltd. यह घोषणा करती है कि HeartSine samaritan PAD Trainer* में नरिदेशिका 2014/53/EU का पालन किया गया है।
• फ्रीक्वेंसी बैंड: 2412-2472 मेगाहर्ट्ज (MHz)
• रेडियो फ्रीक्वेंसी पावर: 20 डीबीएम से ज्यादा नहीं

ZH-TW: HeartSine Technologies, Ltd. 在此聲明 HeartSine samaritan PAD Trainer* 遵循指令 2014/53 / EU 。
• 頻段：2412-2472 兆赫 (MHz)
• 射頻能：不超過 20 dbm

HR: Tvrtka HeartSine Technologies, Ltd. ovime izjavljuje da je uređaj HeartSine samaritan PAD Trainer* sukladan s Direktivom 2014/53/EU.
• Frekvencijski pojasi: 2412-2472 megaherca (MHz)
• Radiofrekvencijska snaga: ne veća od 20 dBm

HU: A HeartSine Technologies, Ltd. ezennel kijelenti, hogy a HeartSine samaritan PAD Trainer* megfelel a 2014/53/EU irányelv rendelkezéseinek.
• Frekvenciasávok: 2412-2472 megahertz (MHz)
• Rádiófrekvenciás teljesítmény: Nem nagyobb, mint 20 dbm

ID: Dengan ini, HeartSine Technologies, Ltd. menyatakan bahwa HeartSine samaritan PAD Trainer* telah sesuai dengan Direktif 2014/53/EU.
• Pita frekuensi: 2412-2472 megahertz (MHz)
• Daya frekuensi radio: Tidak lebih dari 20 dbm

IS: HeartSine Technologies, Ltd. lýsir því hér með yfir að HeartSine samaritan PAD Trainer* samræmist tilskipun 2014/53/ESB.
• Tiðnisvið: 2412–2472 megarið (MHz)
• Fjarskiptatiðni: Ekki yfir 20 dbm

IT: Con il presente documento, HeartSine Technologies, Ltd. dichiara che HeartSine samaritan PAD Trainer* è conforme alla Direttiva 2014/53/UE.
• Bande di frequenza: 2412-2472 megahertz (MHz)
• Potenza di radiofrequenza: Non superiore a 20 dbm

JA: HeartSine Technologies, Ltd.は、HeartSine samaritan PAD Trainer*がDirective 2014/53/EUに準拠していることをここに宣言します。

- 周波数帯域：2412～2472メガヘルツ（MHz）
- 高周波電力：20 dbm以下

KO: 본 문서를 통해, (주) 하트사인 테크놀로지스(HeartSine Technologies)는 당사제품 HeartSine samaritan PAD Trainer* 가 아래 사양을 통해 EU 무선기기지침 2014/53/EU를 준수했음을 확인함.

- 주파수 대역: 2412-2472 MHz
- 최대 무선주파수 출력: 20 dBm 미만

LT: „HeartSine Technologies, Ltd.“ pareiškia, kad „HeartSine samaritan PAD Trainer“* atitinka Direktyvos 2014/53/ES nuostatas.

- Dažnių juostos: nuo 2412 iki 2472 megahercų (MHz)
- Radijo dažnių galia: ne daugiau nei 20 dbm

LV: Ar šo uzņēmums HeartSine Technologies, Ltd. apliecina, ka HeartSine samaritan PAD Trainer* atbilst direktīvas 2014/53/ES prasībām.

- Frekvences joslas: 2412–2472 megaherci (MHz)
- Radiofrekvences jauda: ne vairāk par 20 dBm

ZH-CN: HeartSine Technologies, Ltd. 特此声明，HeartSine samaritan PAD Trainer* 符合 2014/53/EU 指令。

- 频段：2412 至 2472 兆赫 (MHz)
- 射频频率：不大于 20 dbm

MS: Dengan ini, HeartSine Technologies, Ltd. menyatakan bahawa HeartSine samaritan PAD Trainer* mematuhi Arahan 2014/53/EU.

- Jalur frekuensi: 2412-2472 megahertz (MHz)
- Kuasa frekuensi radio: Tidak melebihi 20 dbm

NL: HeartSine Technologies, Ltd. verklaart hierbij dat de HeartSine samaritan PAD Trainer* voldoet aan Richtlijn 2014/53/EU.

- Frequentiebanden: 2412–2472 megahertz (MHz)
- Radiofrequentievermogen: Niet groter dan 20 dbm

NO: HeartSine Technologies, Ltd. erklærer herved at HeartSine samaritan PAD Trainer* samsvarer med direktivet 2014/53/EU.

- Frekvensbånd: 2412-2472 megahertz (MHz)
- Radiofrekvenseffekt: Ikke høyere enn 20 dbm

PL: Firma HeartSine Technologies, Ltd. niniejszym deklaruje, że moduł HeartSine samaritan PAD Trainer* jest zgodny z Dyrektywą 2014/53/UE.

- Pasma częstotliwości: 2412–2472 megaherców (MHz)
- Moc częstotliwości radiowej: Nie więcej niż 20 dbm

PT-PT: A HeartSine Technologies, Ltd. declara por este meio que o HeartSine samaritan PAD Trainer* está em conformidade com a Diretiva 2014/53/UE.

- Bandas de frequência: 2412-2472 mega-hertz (MHz)
- Potência de radiofrequência: não superior a 20 dbm

RO: Prin prezenta, HeartSine Technologies, Ltd. declară că HeartSine samaritan PAD Trainer* este în conformitate cu Directiva 2014/53/UE.

- Benzi de frecvență: 2412-2472 megahertzi (MHz)
- Putere frecvență radio: Nu mai mult de 20 dbm

RU: Настоящим компания HeartSine Technologies, Ltd. заявляет, что продукт HeartSine samaritan PAD Trainer* соответствует требованиям Директивы 2014/53/ЕС.

- Частотные диапазоны: 2412–2472 МГц
- Радиочастотная мощность: Не более 20 дБм

SL: Podjetje HeartSine Technologies, Ltd. s tem izjavlja, da je izdelek HeartSine samaritan PAD Trainer* skluden z Direktivo 2014/53/EU.

- Frekvenčni pasovi: 2412–2472 megahertz (MHz)
- Energija za radijsko frekvenco: ne presega 20 dbm

SV: HeartSine Technologies, Ltd. deklarerar härmed att HeartSine samaritan PAD Trainer* följer direktivet 2014/53/EU.

- Frekvensband: 2412-2472 megahertz (MHz)
- Radiofrekvensstyrka: Inte högre än 20 dbm

TH: บริษัท HeartSine Technologies, Ltd. ขอประกาศไว้ ณ ที่นี้ว่า HeartSine samaritan PAD Trainer* นั้นได้เป็นไปตามมาตรฐาน Directive 2014/53/EU

- แถบความถี่: 2412-2472 เมกะเฮิรตซ์ (MHz)
- กำลังส่งคลื่นวิทยุ: ไม่เกิน 20 dbm

TR: HeartSine Technologies, Ltd., HeartSine samaritan PAD Trainer* in 2014/53/AB sayılı Direktife uygun olduğunu beyan eder.

- Frekans bantları: 2412-2472 megahertz (MHz)
- Radyo frekans gücü: 20 dbm'den büyük değil

VI: Qua đây, công ty TNHH Công nghệ HeartSine xin thông báo rằng sản phẩm HeartSine samaritan PAD Trainer* tuân thủ đúng theo chỉ thị 2014/53/EU

- Các dải tần số: 2412-2472 Mê ga héc (MHz)
- Công suất tần số của radio: Không được lớn hơn 20 dbm

*TRN-350-XX (TRN-ACC-16), TRN-360-XX (TRN-ACC-18), TRN-450-XX (TRN-ACC-19), TRN-500-XX (TRN-ACC-17)

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12. Revision history

Rev	Description
AA	Originate Document
AB	<p>In main body of text all mention of 'HeartSine Gateway' has been updated to 'HeartSine Trainer'</p> <p>Date of Issue changed from '2020/06' to '04/2021'</p> <p>Copyright of '2020' updated to '2021'</p> <p>Rev of '0' updated to 'AB'</p>
AC	<p>Throughout the insert 'HeartSine® Trainer' has been updated to 'HeartSine® samaritan® PAD Trainer'</p> <p>Country Codes updated throughout – AS updated to ES-LA; BZ updated to PT-BZ; CZ updated to CS; EE updated to ET; ES updated to ES-ES; HK updated to ZH-TW; MD updated to ZH-CN; PO updated to PL and PT updated to PT-PT</p> <p>Addition of 'Stryker or its affiliated entities own, use, or have applied for the following trademarks or service marks: HeartSine, samaritan, Stryker. All other trademarks are trademarks of their respective owners or holders. The absence of a product, feature, or service name, or logo from this list does not constitute a waiver of Stryker's trademark or other intellectual property rights concerning that name or logo.' On page 6</p> <p>Footer updated to include updated date of issue and updated rev AC</p> <p style="text-align: center;">Address updated throughout to 'HeartSine Technologies, Ltd. 207 Airport Road West Belfast Northern Ireland BT3 9ED United Kingdom'</p>

Note: If this section is used, list no more than five (5) previous revisions.