This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The device covered by the present Declaration is in conformity with all regulations or directives below, including compliance with related Essential Requirements and General Safety and Performance Requirements.

1. Object of the declaration:

<table>
<tr><td>Product Name</td><td>MONITOR/DEFIBRILLATOR</td></tr>
<tr><td>Product Type</td><td>HeartStart Intrepid</td></tr>
<tr><td>Intended Purpose</td><td>The HeartStart Intrepid is intended for use in an EMS or hospital setting by qualified medical personnel trained in the operation of the device and qualified by certified training in basic life support or advanced life support. This HeartStart Intrepid is intended for use in emergency resuscitation as follows:
•In AED Mode, to detect a shockable rhythm and deliver a shock
•In Manual Mode, to deliver synchronized and asychronized defibrillation.
•The optional Q-CPR meter 2 to provide the user feedback in performing chest compression during CPR
•In Pacing Mode to deliver external cardiac pacing
•In Monitor Mode, the Intrepid is intended to
–measure heart rate and heart rhythm via ECG
–measure blood oxygen saturation via SpO2
–measure exhaled CO2 via EtCO2
–measure systolic, diastolic, and mean blood pressure via NBP
–measure temperature</td></tr>
<tr><td>Product Part Number(s) and Descriptions</td><td>867172 HeartStart Intrepid</td></tr>
<tr><td>Product Options/Accessories Part Number(s) and Descriptions</td><td>This declaration also includes the following product options and accessories:
<table><tr><th>Part Number</th><th>Description</th></tr><tr><td>989803202601</td><td>Lithium Ion Battery</td></tr><tr><td>989803206451</td><td>Intrepid Li-ion Battery</td></tr><tr><td>989803202931</td><td>DC power module</td></tr><tr><td>989803197111</td><td>Pads adapter cable, 2.1 m</td></tr><tr><td>989803158661</td><td>Hands-free pads cable, Q-CPR, HeartStart connector only (plug-style), 2.2 m</td></tr></table></td></tr>
<tr><td>Basic UDI-DI</td><td>0884838BM472T7</td></tr>
<tr><td>Control Indicator</td><td>effective date
<table><tr><td>Initial Issue Date:</td><td>Part Number:</td></tr></table></td></tr>
</table>

	• 16-July-2019	• 867172
Global Medical Device Nomenclature Code (GMDN) and Description or CND Code and Description	CND code: Z120305 Description: Defibrillators	

The object of the Declaration described above is in conformity with the following regulations:

EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical devices amended up to and inclusive of Council Directive 2007/47/EC (MDD)**
Device Risk Classification	Class IIb based on Annex IX and Rule 9
Conformity Assessment Path	Annex II excluding (4)
Notified Body Name, Address, and ID	NB name: TÜV SÜD Product service GmbH NB address: TÜV SÜD Product service GmbH Ridlerstr 65, D-80339 München, Germany NB ID: 0123
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A.

EU Directive	**Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS)**
Device Classification	Category 8

Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A

EU Directive	**Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (RED)**
Device Classification	Class I
Conformity Assessment Path	Annex II Conformity Assessment Module A
Notified Body Name, Address, ID and EU Certificate Number	TUV certification: No. T8EA 036155 0065 Rev.00 Issued by: TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße65 • 80339Munich • Germany
Standards	The radio equipment was tested to the following standards or technical specifications: Refer to Attachment A

2. Additional information:

Manufacturer	Philips Goldway (Shenzhen) Industrial Inc. No.2 Keji North 3rd Road, Nanshan District, 518057 Shenzhen PEOPLE'S REPUBLIC OF CHINA

EU Authorized Representative	Shanghai International Holding Corp.GmbH(Europe) Eiffestra ße 80, 20537 Hamburg, Germany
Quality Certificates Issued	The Manufacturer is certified by TÜV SÜD PRODUCT SERVICE GMBH to the following: EN ISO 13485: 2016 Certificate no. Q5 0361550062 Rev. 00 EC certificate no. G1 0361550041 Rev. 01

Signature (signed for and on behalf of Philips Goldway (Shenzhen) Industrial Inc.):

Date of Issue: 28-June-2022

Printed Name: Mandy Mi

Place of Issue: Shen Zhen, P.R. CHINA

Title: RA manager

Doc ID: A-867172-DOC Rev K

Mandy. Mi

3. Attachment A

Standards and/or Common Specifications

Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Risk management	
EN ISO14971:2019	Medical Device Risk Management - International Edition
Software Life Cycle	
EN 62304:2006+A1:2015	Medical device software – Software life-cycle processes
Usability Engineering	
EN 62366-1:2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
Biological Evaluation	
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4:2017	Biological evaluation of medical devices. Part 4: Selection of tests for interactions with blood
EN ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
Labeling	
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
IEC TR 60878:2015	Graphical symbols for electrical equipment in medical practice
EN ISO 780:2015	Packaging - Pictorial marking for the handling of goods
Road ambulances	
EN 1789:2020	Medical vehicles and their equipment - Road ambulances
Radio equipment	
ETSI EN 301 489-1 V2.2.3	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility;

ETSI EN 301 489-17 V3.2.4	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility;
ETSI EN 300 328 V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum;
ETSI EN 301 893 V2.1.1	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU;
EN 50385:2017	Product standard to demonstrate the compliance of base station equipment with radiofrequency electromagnetic field exposure limits (110 MHz - 100 GHz), when placed on the market
General Safety Standard	
EN 60601-1: 2006 + A2:2021	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Collateral Safety Standards	
EN 60601-1-6:2010/ A2:2021	Medical electrical requirements for basic safety and essential performance – Collateral Standard: Usability
EN 60601-1-2:2015 /A1:2021	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-8:2007 /A2:2021	Medical electrical equipment – Part 1-8: General requirements for safety – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical requirement and medical electrical systems
EN 60601-1-12: 2015/A1:2020	Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
Particular Safety Standards	
EN 60601-2-27: 2014	Medical electrical equipment – Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
EN IEC 80601-2-49: 2019	Medical electrical equipment – Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

EN 60601-2-25:2015	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
EN IEC 80601-2-30:2019	Medical electrical equipment. Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 80601-2-61:2019	Medical Electrical Equipment – Part 2-61: Particular Requirements for the Basic Safety of Essential Performance of Pulse Oximeters
EN ISO 80601-2-55:2018	Medical Electrical Equipment – Part 2-55: Particular Requirements for the Basic Safety of Essential Performance of Respiratory Gas Monitors
EN 60601-2-4:2011+ A1:2019	Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
EN ISO 80601-2-56:2017/ A1:2020	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
EN ISO 81060-2:2019 /A1:2020	Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type