1. Object of the declaration:

Product Name	DEFIBRILLATOR/MONITOR
Product Type	Efficia DFM100
Intended Purpose	The Efficia DFM100 is intended for use in a hospital or EMS setting by users trained in the operation of the device and qualified by training in BLS and ALS. The Efficia DFM100 is intended for use for emergency resuscitation as follows: • In AED mode, the Efficia DFM100 is intended to detect a shockable rhythm and deliver a shock. • In Manual mode, the Efficia DFM100 is intended to deliver synchronized and asychronized defibrillation. • In Pacing mode, the Efficia DFM100 is intended to deliver external cardiac pacing. • In Monitor mode, the Efficia DFM100 is intended to measure heart rate and heart rhythm via ECG, measure blood oxygen saturation via SpO_2, measure exhaled CO_2 via $EtCO_2$, and measure systolic, diastolic, and mean blood pressure via NBP.
Product Part Number(s) and Descriptions	866199 Efficia DFM100
Product Options/Accessories Part Number(s) and Descriptions	This declaration also includes the following product options and accessories: Part Number: 989803190371 — DFM100 Lithium Ion Battery Part Number: 989803197111 — DFM100 Pads Adapter Cable
Basic UDI-DI	0884838BM471T5
Control Indicator	Effective date: Initial Issue Date: • 21-July-2014 Part Number: • 866199
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

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) Eiffestraβe 80, 20537 Hamburg, Germany

PHILIPS

EU Declaration of Conformity for Efficia DFM100

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: 10-May-2023

Printed Name: Mandy Mi

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

Title: RA manager

Doc ID: A-866199-DoC Rev H

Mandy. Mi

Date of Expiration 26-May-2024

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 ISO 14971:2019	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
Processing	
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical 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
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
EN 60601-1-9:2013	Medical electrical equipment. Part 1-9: General requirements for basic safety and essential performance. Collateral Standard: Requirements for environmentally conscious design
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 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 81060-2:2019/ A1:2020	Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type
EN 1789:2020	Medical vehicles and their equipment – Road ambulance