PHILIPS

EU Declaration of Conformity

Philips Medical Systems
22100 Bothell Everett Highway
Bothell, WA 98021-8431, USA

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 below and other relevant Union legislation.

Product Name and Product Part Numbers:

Part Number	Description
861304	HeartStart FRx Defibrillator

Control Indicator:

Products manufactured after 12 May 2021

Global Medical Device Nomenclature Code (GMDN) and Description

47910, Non-Rechargeable Semi-Automated External Defibrillator

Universal Medical Device Nomenclature Code (UMDNS) and Title:

17-116, Defibrillators, Automated, External

Product Options/Accessories:

This declaration also includes the following product options and accessories:

Part Number	GMDN Code	UMDNS Code	Description
989803139311	47910; Non-Rechargeable Semi-Automated External Defibrillator	17-116; Defibrillators, Automated, External	Infant/Child Key

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
Device Risk Classification	Class IIb based on Annex IX and Rule 9
Conformity Assessment Path	Annex II excluding (4)
Name/Address/ID of Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München Germany NB# 0123

Standards	The following standards have been used to demonstrate conformity with applicable essential requirements set out in Annex I of the Medical Devices Directive.
	EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices EN ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes EN ISO 14971:2012 – Medical Devices – Application of Risk Management to Medical Devices IEC 60529:1989 + A2:2013 + C1: 2019 – Degrees of protection provided by enclosures (IP Code)

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	IEC 60601-1:2005+A1:2012 – Medical Electrical Equipment – Part I: General requirements for Basic Safety and Essential Performance IEC 60601-1-2:2014 – Medical Electrical Equipment – Part 1-2: General requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and tests IEC 60601-1-6:2010+A1:2013 – Medical Electrical Equipment – Part 1-6: General requirements for Basic Safety and Essential Performance – Collateral standard: Usability IEC 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 IEC 60601-1-11: 2015 - MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 60601-1-12:2014 - 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 IEC 60601-2-4:2010 – Medical Electrical Equipment – Part 2-4: Particular requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators IEC 62304:2006 – Medical Device Software – Software life-cycle processes IEC 62366-1:2015 – Medical Devices – Application of Usability engineering to Medical Devices ISO 15223-1:2016 – Medical Devices – Symbols to be used with Medical Device labels, labelling and information to be supplied – Part 1: General requirements RTCA DO-160G - Environmental Conditions and Test Procedures for Airborne Equipment

Additional information:

EU Authorized Representative:	Philips Medizin Systeme Böblingen GmbH Hewlett-Packard Str. 2 71034 Böblingen Germany
Quality Certificates Issued:	EN ISO 13485:2016 Quality Management Systems by TÜV SÜD with the certificate number Q5 078838 0012 Rev. 00 EC Certificate – Full Quality Assurance System by TÜV SÜD with the certificate number G1 078838 0014 Rev. 00

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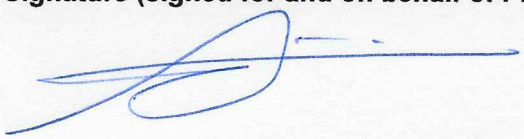
Signature (signed for and on behalf of Philips):



(Refer to signed PDF)
Printed Name: Michael F. Petrini, MS, RAC
Title: Head, Regulatory Affairs – EC

Date of Issue:

12 May 2021

(Refer to signed PDF)
Valid Until: 26 May 2024
Place of Issue: Bothell, WA