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:

HeartStart FRx, Model 861304

Product Part Numbers:

Model 861304

Control Indicator:

Serial Number: B16F-00097

Global Medical Device Nomenclature Code (GMDN) and Description

Part Number	GMDN Code
861304	47910, Non-rechargeable semi-automated external defibrillator
M5070A	38558, Primary battery
989803139301	38558, Primary battery
989803139311	47910, Non-rechargeable semi-automated external defibrillator

Universal Medical Device Nomenclature Code (UMDNS) and Title:

Part Number	UMDNS Code
861304	17-116, Defibrillators, Automated, External
M5070A	16-640, Batteries
989803139301	16-640, Batteries
989803139311	17-116, Defibrillators, Automated, External

Product Options/Accessories:
This declaration also includes the following product options and accessories:

Part Number	Description
M5070A	Primary Battery Pack
989803139301	FAA TSO C-142 Compliant Battery Pack
989803139311	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 Rule 9
Conformity Assessment Path	Annex II

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Name/Address/ID of Notified Body	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstrabe 65 80339 München Germany NB# 0123

The following standards have been used to demonstrate conformity with applicable essential requirements set out in Annex I of the Medical Devices Directive.

Standard	Title
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
EN 60529:1991/A2:2013	Degrees of protection provided by enclosures (IP Code)
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 62366-1:2015	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-4:2010	Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 62304:2006	Medical device software – Software life-cycle processes
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

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 System 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 17 05 78838 007

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Signature (signed for and on behalf of Philips):

Date of Issue:

03 Mar 2019

Printed Name: Michael Petrini

Valid Until: 07/05/2021

Title: Regulatory Affairs Manager, ECR, Philips

Place of Issue: Bothell, WA