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 Adult Smart Pads Cartridge
HeartStart Infant/Child Smart Pads Cartridge

Product Part Numbers:

Part Number	Description
M5071A	HeartStart Adult Smart Pads Cartridge
M5072A	HeartStart Infant/Child Smart Pads Cartridge

Control Indicator:
Products manufactured after 09 Nov 2020

Global Medical Device Nomenclature Code (GMDN) and Description:

Part Number	GMDN Code	Code Description
M5071A	44771	External Defibrillator Electrode, Adult, Single-Use
M5072A	41587	External Defibrillator Electrode, Pediatric, Single-Use

Universal Medical Device Nomenclature Code (UMDNS) and Title:
15-033 Electrodes, Defibrillation

Product Options/Accessories:
N/A

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 Zertifizierstelle Ridlerstrabe 65 D- 80339 Munchen Germany NB# 0123

Standards	**The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the product standards listed below:**
	EN 1041:2008+A1:2013 – Information supplied by the manufacturer with medical devices EN ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

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	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) 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 60601-2-4:2010 – Medical Electrical Equipment – Part 2-4: Particular requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators 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 ISO 10993-1:2009/Cor 1:2010 – Biological evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 - Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 - Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

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):

Printed Name: Zachary Price
Title: Regulatory Affairs Program Manager, ECR

Date of Issue:

09-NOV-2020

Valid Until: 26 May 2024
Place of Issue: Bothell, WA