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 SMART Pads II

Product Part Numbers:
989803139261

Control Indicator:
Lot # 190814-0950

Global Medical Device Nomenclature Code (GMDN) and Description:
45806 Multi-function cardiac electrode, adult

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

Product Options/Accessories:
None

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

EU Directive	**Council Directive 93/42/EEC as amended through 2007/47/EC**
Device Classification	Class I based on Annex IX and Rule 1
Conformity Assessment Path	Annex VII
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 ISO 13485:2016 Quality Management System EN ISO 14971:2012 – Medical Devices - Application of Risk Management to Medical Devices IEC 60601-1:2005+A1:2012 – Medical electrical equipment-Part 1: 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 60601-2-4:2010 – Medical electrical equipment, Part 2: Particular Requirements for the Safety of Cardiac Defibrillators and Cardiac Defibrillator/monitors

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EU Directive	Council Directive 93/42/EEC as amended through 2007/47/EC
	EN IEC 62366-1:2015 - Medical devices -- Part 1: Application of usability engineering to medical devices ISO 10993-1:2009 – 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: Irritation and Sensitization EN ISO 15223-1:2016 – Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (called out in IEC 60601-2-4). 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

Signature (signed for and on behalf of Philips):

Printed Name: Michael Petrini

Title: Regulatory Affairs Manager, ECR, Philips

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