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 HS1

**Product Part Numbers:**

Model M5066A - HeartStart HS1 or Onsite Automated External Defibrillator (AED)
Model M6070A – Primary Battery

**Control Indicator:**

Serial Number: A16D-00001

**Global Medical Device Nomenclature Code (GMDN) and Description**
47910 - Non-rechargeable semi-automatic external defibrillator
38558 - Primary Battery

**Universal Medical Device Nomenclature Code (UMDNS) and Title:**
17-116 - Defibrillators, Automated, External
16-640 - Batteries

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

| Part Number | Description |
|---|---|
| M5070A | Primary Battery Pack |

**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 |
| **Name/Address/ID of Notified Body** | TUV SUD Product Service GMBH<br>Zertifizierstelle<br>Ridlerstrabe 65<br>80339 Munchen<br>Germany<br>NB# 0123 |

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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 13485:2012 | 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 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 |
| ISO 15223-1:2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements |
| EN 1041:2008+A1:2013 | Information supplied by the manufacturer of medical devices |
| IEC 62366-1:2015 | Medical devices – Application of usability engineering to medical devices |

**Additional information:**

| | |
|---|---|
| **EU Authorized Representative**: | Philips Medizin Systeme Böblingen GmbH<br>Hewlett-Packard Str. 2<br>71034 Böblingen<br>Germany |
| **Quality Certificates Issued**: | ISO 13485:2012 + AC:2012 Quality Management System by TUV SUD with the certificate number Q1N 17 11 78838 011<br><br>EC Certificate – Full Quality Assurance System by TUV SUD with the certificate number G1 17 05 78838 007 |

**Signature (signed for and on behalf of Philips)**:

**Printed Name** Maxs Newberry
**Title:** Regulatory Affairs Manager, ECR, Philips

**Date of Issue:** 02/13/2019

**Valid Until:** 07/05/2021
**Place of Issue:** Bothell, WA