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 or Onsite Automated External Defibrillator

**Product Part Numbers:**

M5066A

**Control Indicator:**

Production date starting 10 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:

N/A

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

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| 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 excluding (4) |
| Name/Address/ID of Notified Body | TUV SUD Product Service GMBH<br>Ridlerstrasse 65<br>D- 80339 München<br>Germany<br>NB# 0123 |

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| 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 of Medical Devices<br><br>EN ISO 13485:2016 - Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes<br><br>EN ISO 14971:2012 - Medical Devices – Application of Risk Management to Medical Devices<br><br>IEC 60529:1989/A2:2013 / C1:2019 - Degrees of protection provided by enclosures (IP Code)<br><br>IEC 60601-1:2005+A1:2012 - Medical Electrical Equipment – Part I: General requirements for Basic Safety and Essential Performance<br><br>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<br><br>IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances<br><br>IEC 60601-1-6:2010+A1:2013 - Medical Electrical Equipment – Part 1-6: General requirements for Basic Safety and Essential Performance – Collateral standard: Usability<br><br>IEC 60601-2-4:2010 - Medical Electrical Equipment – Part 2-4: Particular requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators<br><br>IEC 62304:2006+A1:2015 - Medical Device Software – Software life-cycle processes<br><br>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 |

**Additional information:**

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| **EU Authorized Representative**: | Philips Medizin Systeme Böblingen GmbH<br>Hewlett-Packard Str. 2<br>71034 Böblingen<br>Germany |

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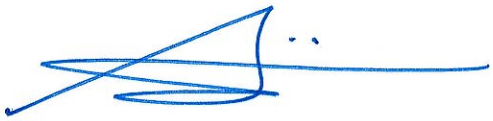
| **Quality Certificates Issued**: | ISO 13485:2016: Quality Management Systems by TUV SUD with the certificate number Q5 078838 0012 Rev. 00<br>EC Certificate – Full Quality Assurance System by TUV SUD with the certificate number G1 078838 0014 Rev. 00 |

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



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

**Date of Issue:**

24 Aug 2021

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