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 and Product Part Numbers:

Part Number	Description
861304	HeartStart FRx Defibrillator

Control Indicator:

Products manufactured after 22 Mar 2022

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:

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 Ridlerstrasse 65 D-80339 München Germany NB# 0123

Standards	The following standards have been used to demonstrate conformity with applicable essential requirements set out in Annex I of the Medical Devices Directive.
	EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices 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 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 l: General requirements for Basic Safety and Essential Performance

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Standards	The following standards have been used to demonstrate conformity with applicable essential requirements set out in Annex I of the Medical Devices Directive.
	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 60601-1-9:2013 - Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design 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 IEC 60601-1-12:2014 - Medical electrical equipment- Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment 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 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 RTCA DO-160G - Environmental Conditions and Test Procedures for Airborne Equipment

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 0016 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: Nadine Smith
Title: Regulatory Affairs Program MGR – Emergency Care

Date of Issue:

Valid Until: 12 Apr 2025
Place of Issue: Bothell, WA

Record Identification: LC0285-101-001

PHILIPS

Attachment to Declaration of Conformity – HeartStart FRx

Declaration of Conformity Document Number/Rev.:	LC0285-101 Rev. AB
Description of the change:	The HeartStart FRx is in conformance with IEC 60601-2-4:2010+AMD1:2018 – Medical Electrical Equipment – Part 2-4: Particular requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators.
Assessment:	This change was assessed per "MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD." Updated standard reference to the newer revision of the standard IEC 60601-2-4:2010+ AMD1:2018 per LC0393-204, FRx IEC 3rd Edition CSA Certification. This change was implemented to qualify an alternate supplier for High Voltage Capacitor (component) and was determined to be non-significant per the EU MDR Article 120 and MDCG 2020-3 Guidance.

Signature (signed for and on behalf of Philips Medical Systems)

Nadine Smith

Regulatory Affairs Program Manager – Emergency Care

15 Jun 2022

Date of Issue: 15Jun2022

Place of Issue: Bothell, WA

Document #: LC0285-101

Date of Expiration: 26 May 2024

Record Identification: LC0285-101-002

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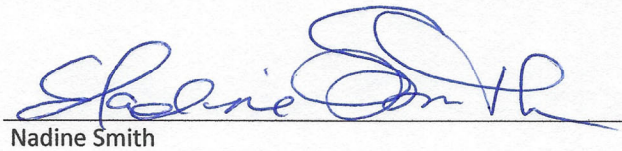
Attachment to Declaration of Conformity - HeartStart FRx

Declaration of Conformity Document Number/Rev.:	LC0285-101 Rev. AB
Description of the change:	A minor design change was made to replace an obsolete component. The new control indicator is product manufactured on or after 14Sep2022.
Assessment:	This change has been assessed per MDCG 2020-3 guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD. This change has been deemed to be non-significant.

Signature (signed for and on behalf of Philips Medical Systems)



13 Oct 2022

Nadine Smith

Regulatory Affairs Program Manager – Emergency Care

Date of Issue: 13Oct2022

Place of Issue: Bothell, WA

Document #: LC0285-101-102

Date of Expiration: 26 May 2024