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EU Declaration of Conformity for HeartStart Batteries

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 and directives below, including compliance with the General Safety and Performance Requirements.

1 Object of the declaration:

Product Name	HeartStart Batteries
Product Type	Defibrillator Batteries
Intended Purpose	The HeartStart Batteries do not have an intended purpose by themselves without the parent AED but are intended to provide electrical battery power to the parent AED.
Product Part Number(s) and Descriptions	

Part Number	Description
HeartStart HS1 and FRx	
M5070A	Primary Battery
HeartStart FRx	
989803139301	FRx Aviation Battery Pack
HeartStart FR3	
989803150161	Primary Battery
989803150171	FR3 Aviation Battery Pack
989803150241	Secondary Rechargeable Battery

Product Options/Accessories Part Number(s) and Descriptions	None
Basic UDI-DI	0884838BM479TM
Control Indicator	

Part Number	Control Indicator
HeartStart HS1 and FRx	
M5070A	Release dates: 20May2021 through 11Jan2024 Initial release date: 19Jan2024
HeartStart FRx	
989803139301	Release dates: 21Sep2021 through 11Jan2024 Initial release date: 19Jan2024
HeartStart FR3	
989803150161	Initial release date: 20May2021
989803150171	Beginning Lot number: GB6994605
989803150241	Initial release date: 24Apr2023

EMDN Code and Description	Z12030580: Defibrillators – Hardware

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The object of the Declaration described above is in conformity with the following regulations/directives:

EU Regulation	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices (EU MDR)**
Device Risk Classification	Class I based on Annex VIII and Rule 1
Conformity Assessment Path	Not applicable for Class I medical devices
Notified Body Name, Address, and ID	Not applicable for Class I medical devices
Certificate(s) issued	Not applicable for Class I medical devices
Standards	Refer to Attachment A
Common Specifications	None. There are no common specifications for specified devices.

EU Directive	**Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) Text with EEA relevance.**
Philips has implemented a sustainable financing scheme which guarantee the effective and environmentally sound collection and recycling of WEEE, according to Article 12.4 of the WEEE Directive.	

EU Regulation	**Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC**
Specified devices meet requirements of Regulation (EC) No 1907/2006 REACH as defined in the regulated substances list scope provided on Philips website.	

EU Directive	**Directive 2013/56/EU of the European Parliament and of the Council amending Directive 2006/66/EC of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators as regards the placing on the market of portable batteries and accumulators containing cadmium intended for use in cordless power tools, and of button cells with low mercury content.**
Specified devices meet requirements of Directive 2013/56/EU as defined in the regulated substances list scope provided on Philips website.	

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2 Additional information:

Manufacturer	Philips Medical Systems 22100 Bothell Everett Highway Bothell, WA 98021-8431 USA SRN: US-MF-000002128
EU Authorized Representative	Philips Medical Systems Nederland B.V. Veenpluis 6 5684PC Best The Netherlands SRN: NL-AR-000001422
Quality Certificates Issued	The Manufacturer is certified by TÜV SÜD to the following: • EN ISO 13485:2016 Quality Management: Q5 078838 0016 Rev. 01 • MDSAP Certificate by TÜV SÜD: QS6 078838 0013 Rev. 02

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

Printed Name: Nadine Smith
Title: Regulatory Affairs Program Manager

Date of Issue: 02Feb2024

02Feb2024

Place of Issue: Bothell, WA
Document#: LC2381-201
Date of Expiration: 05Dec2026

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Attachment A - Standards and/or Common Specifications

Applied Standards and Guidance for the HeartStart HS1 and FRx Batteries:

Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Labeling Standards	
EN ISO 20417:2021	Medical Devices – Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical devices labels, labelling and information to be supplied — Part 1: General requirements
General Safety Standard	
IEC 60601-1:2005+A1:2012	Medical electrical equipment. Part 1: General requirements for basic safety
Collateral Safety Standards	
IEC 60601-1-2:2014	Medical electrical equipment. Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
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
Usability Standards	
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-6:2010+A1: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
Particular Safety Standards	
IEC 60601-2-4:2010 +A1:2018	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
IEC 60086-4:2019	Primary batteries – Part 4: Safety of lithium batteries
Risk Management Standard	
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
Transportation	
ST/SG/AC. 10/11/Rev.6/Amd 1 (UN/DOT 38.3)	Recommendations on the Transport of Dangerous Goods – Manual of Tests and Criteria
FRx Aviation Battery Only	
RTCA DO-160G	Environmental Conditions and Test Procedures for Airborne Equipment
TSO-C142, RTCA/DO-227:2017	Technical Standard Order – Lithium Batteries, Minimum Operational Performance Standards for Lithium Batteries
Guidance	
MEDDEV 2.7/1 Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC. Guidelines on Medical Devices

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Applied Standards and Guidance for the HeartStart FR3 Batteries:

Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
Labeling Standards	
EN ISO 15223-1:2021	Medical Devices – Symbols to be used with medical devices labels, labelling and information to be supplied — Part 1: General requirements
General Safety Standard	
IEC 60601-1:2005+A1:2012	Medical electrical equipment. Part 1: General requirements for basic safety
Collateral Safety Standards	
IEC 60601-1-2:2014	Medical electrical equipment. Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
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
Particular Safety Standards	
IEC 60601-2-4:2010 +A1:2018	Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators
Usability Standards	
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 60601-1-6:2010+A1: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
Risk Management Standard	
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
Transportation	
ST/SG/AC. 10/11/Rev.6/Amd 1 (UN/DOT 38.3)	Recommendations on the Transport of Dangerous Goods – Manual of Tests and Criteria
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
FR3 Aviation Battery Only	
RTCA DO-160G	Environmental Conditions and Test Procedures for Airborne Equipment
TSO-C142, RTCA/DO-227:2017	Technical Standard Order – Lithium Batteries, Minimum Operational Performance Standards for Lithium Batteries
Guidance	
MEDDEV 2.7/1 Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC. Guidelines on Medical Devices