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EU Declaration of Conformity for Infant/Child Keys

This Declaration of Conformity is issued under the sole responsibility of the manufacturer. The devices covered by the present Declaration are in conformity with all regulations or directives referenced below, including compliance with relevant General Safety and Performance Requirements.

1 Object of the declaration:

Product Name	Infant/Child Key (989803139311) FR3 Infant/Child Key (989803150031)
Product Type	A medical device accessory (hardware key for pediatric use) to the HeartStart FRx and HeartStart FR3 Defibrillators.
Intended Purpose	The Infant/Child Keys do not have an intended purpose by themselves without the parent defibrillator.
Product Part Number(s) and Descriptions	• Infant/Child Key 989803139311 • FR3 Infant/Child Key 989803150031 Infant/Child Keys are optional accessories to the HeartStart FRx and HeartStart FR3 Defibrillators for customers who may need the capability of treating infants and children under 55 pounds (25 kg) or 0-8 years old. When the Infant/Child Key is inserted into the designated defibrillator port/slot it reduces the energy from 150 J to 50 J for infant/child use and initiates infant/child CPR guidance.
Product Options/Accessories Part Number(s) and Descriptions	Not applicable. The Infant/Child Key does not contain accessories within the scope of the EU MDR Regulations.
Basic UDI-DI	0884838BM517T4
Control Indicator	Lot number/Effective date: / Part Number: Beginning with lot: 2003269 / 989803139311 (Infant Child Key) Beginning effective date: 09-Jan-2023 / 989803150031 (FR3 Infant/Child Key)
Global Medical Device Nomenclature Code (GMDN) and Description of EMDN Code and Description	EMDN: Z12030585 Defibrillators – Consumables Infant/Child Key (989803139311) GMDN: 47910 / Non-rechargeable public semi-automated external defibrillator FR3 Infant/Child Key (989803150031) GMDN: 48048 / Rechargeable professional automated external defibrillator

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

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, Rule 1
Conformity Assessment Path	Not applicable for a Class I medical device that is non-sterile, non-reusable or without measuring function.
Notified Body Name, Address, and ID	Not applicable for a Class I medical device that is non-sterile, non-reusable or without measuring function.
Certificate(s) issued	Not applicable for a Class I medical device that is non-sterile, non-reusable or without measuring function.
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below.Refer to Attachment A
Common Specifications	None

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EU Regulation	Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
Device Risk Classification	The Infant/Child Keys do not qualify per Articles 3 and 4 to provide an electronic Instruction for Use only, therefore, per MDR Chapter 3, 23.1(a), a copy of the product IFUs are provided on the Philips eIFU website as a convenience copy only.
Conformity Assessment Path	Not applicable
Notified Body Name, Address, and ID	Not applicable
Certificate(s) issued	Not applicable
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A
Common Specifications	None

2 Additional information:

Manufacturer	Philips Medical Systems 22100 Bothell Everett Highway, Bothell, WA 98021 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

Karuna Velusamy

Digitally signed by Karuna Velusamy
Date: 2024.05.28 14:21:55 -07'00'

Date of Issue: 28 MAY 2024

Printed Name: Karuna Velusamy
Title: Sr. Regulatory Affairs Manager – Emergency Care

Place of Issue: Bothell, WA
LC2388-201
Date of Expiration: 05-DEC-2026

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Attachment A Standards and/or Common Specifications and Other References

Infant Child Key (989803139311):

Quality System	
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
General Safety Standard	
IEC 60601-1:2005 +A1:2012+A2:2020	Medical Electrical Equipment - Part l: General Requirements for Basic Safety and Essential Performance
Collateral Safety Standards	
IEC 60601-1-6:2010 +A1:2013+A2:2020	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
Particular Safety Standards	
IEC 62366:2015+A1:2020	Medical devices - Application of usability engineering to medical devices
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 information to be supplied by the manufacturer - Part 1: General requirements
Risk Management Standards	
EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
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

FR3 Infant Child Key (989803150031):

Quality System	
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
General Safety Standard	
IEC 60601-1:2005 +A1:2012*	Medical Electrical Equipment - Part l: General Requirements for Basic Safety and Essential Performance
Collateral Safety Standards	
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 62366:2015*	Medical devices - Application of usability engineering to medical devices
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 information to be supplied by the manufacturer- Part 1: General requirements
Risk Management Standards	
EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
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

** Philips European Notified Body, TUV SUD, has confirmed that state of the art standards do not need to be applied to accessories for medical devices where the parent device has been discontinued or is no longer manufactured. Such accessories may continue to be placed on the market in the EU with the CE mark until the parent devices reach end of life. Philips FR3 Defibrillator, parent device to the FR3 Infant/Child Key, has been discontinued and is no longer being placed on the market.*