Declaration of Conformity LC0285-101 Rev Z

	Description of Change	Assessment	Effective
1	Removed part number 989803139311, Infant/Child Key from Product Options/ Accessories section of DoC LC0285-101. The Infant/Child Key has transitioned to EU MDR DoC LC2388-201.	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, as non-significant.	16Jul2021
2	New manufacturer for High Voltage Capacitor. Control indicator: Products manufactured after 12Mar2022. Updated ISO 13485:2016 QMS certificate number to Q5 078838 0016 Rev. 00 with expiration date 05Dec2026.	There were no changes to the device design or component performance specifications. 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, as non-significant.	12Apr2022
3	Updated standard conformity to IEC 60601-2-4:2010+A1:2018	This update was implemented when qualifying the alternate supplier for High Voltage Capacitor (component) and was determined to be non-significant 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.	15Jun2022
4	A minor design change was made to replace an obsolete component. Control Indicator: Product manufactured on or after 14Sep2022.	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, as non-significant.	13Oct2022
5	Conformity to updated standard EN ISO 14971:2019	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, as non-significant.	26Jun2023
6	The HeartStart FRx AED contains a battery manufactured by a qualified new supplier. Control Indicator: Initial release date 06Feb2024	This change 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.	06Feb2024
7	Conformity to updated standards IEC 60601-1:2005+A1:2012+A2:2020 IEC 60601-1-2:2014+A1:2020 IEC 60601-1-6:2010+A1:2013+A2:2020 IEC 60601-1-11:2015+A1:2020 IEC 60601-1-12:2014+A1:2020 IEC 62366-1:2015+A1:2020	This update was not due to a material or design change nor was it a change in intended purpose. It 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, as a non-significant change.	17May2024

Declaration of Conformity LC0285-101 Rev Z

Description of Change		Assessment	Effective
8	Based on the confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations EU 2017/745 (MDR) regarding the transitional provisions for certain medical devices, the date of conformity assessment of the HeartStart FRx Defibrillator is extended until 31Dec2027.	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, as non-significant.	22May2024
9	Changed reference of parent Declaration of Conformity from LC0285-101 Rev. AB to LC0285-101 Rev. Z as the final signed DoC prior to the MDR date of application. Consolidated all updates made after 26May2021 into LC0285-101-008 Attachment to LC0285-101 Rev. Z.	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, as non-significant.	16Apr2025

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

Karuna Velusamy

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Reason: I am approving this document
Date: 2025.04.16 15.09.39 -07'00'

Karuna Velusamy

Senior Regulatory Affairs Manager

Date of Issue: 16Apr2025

April 16, 2025

Place of Issue: Bothell, WA

Date of Expiration: 31Dec2027