

Attachment to Declaration of Conformity HeartStart FRx Defibrillator

Declaration of Conformity Document Number/Rev.: LC0285-101/AB

Description of the change 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

Assessment: This change is assessed per the *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* and is considered non-significant.

Additional information: This document replaces LC0285-101-005 which was made obsolete.

Signature (signed for and on behalf of Philips Medical Systems) Date of Issue: 22MAY2024

Karuna Velusamy
Sr. Regulatory Affairs Manager

Place of Issue: Bothell, WA
Date of Expiration: 31DEC2027