

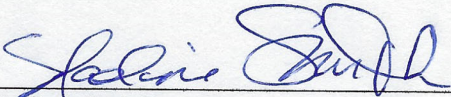
Attachment to Declaration of Conformity – HeartStart FRx

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

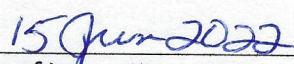
Description of the change: The HeartStart FRx is in conformance with IEC 60601-2-4:2010+AMD1:2018 – Medical Electrical Equipment – Part 2-4: Particular requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators.

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


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