

Attachment to Declaration of Conformity - HeartStart FRx

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

Description of the change: 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

Assessment:

This update is not due to a material or design change nor is 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 or AIMDD, as a non-significant change.

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



Karuna Velusamy

Sr. Regulatory Affairs Manager

17 MAY 2024

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