Declaration of Conformity



Philips Medical Systems 22100 Bothell Everett Highway Bothell, WA 98021-8431 USA

Manufacturer:

Philips Medical Systems

22100 Bothell Everett Highway

Bothell, WA 98021-8431

USA

European Representative:

Philips Medizin Systeme Boeblingen GmbH

Hewlett-Packard Str. 2 71034 Boeblingen

Germany

Notified Body:

TÜV SUD Product Service GMBH

Zertifizierstelle Ridlerstrasse 65 D-80339 München

Germany

NB# 00123

Product Name and/or Model:

HeartStart HS1

Models - M5066A, M5068A

Classification:

Class IIb, Rule 9, Annex II

EU Directive(s):

93/42/EEC concerning medical devices, as amended by 2007/47/EC

GMDN Code and Title:

48047 Non-rechargeable public automated external defibrillator

UMDNS Code and Title:

17116 Defibrillators, Automated, External

Start of CE-marking:

Serial# A12G-03956, July 26, 2012

Product Options/Accessories:

M5070A **Primary Battery Pack** M5071A Adult Pads Cartridge M5072A Infant/Child Pads Cartridge Adult Training Pads Kit M5073A M5074A Infant/Child Training Pads Kit M5075A Standard Carrying Case Slim Carrying Case M5076A M5089A External Manikin Adapter

M5093A Replacement Adult Training Pads Replacement Infant/Child Training Pads M5094A

861487 HeartStart Configure

68-PCHAT Fast Response Kit

Declaration Statement:

We hereby declare that the above mentioned products meet the applicable provisions of 93/42/EEC concerning medical devices, as amended by 2007/47/EC, Class IIb, Rule 9, Annex II, excluding Section 4 which does not apply. An application has not been lodged with any other Notified Body for conformity assessment of the above mentioned products.

Place and Date of Issue:

Bothell, WA August 12, 2015

Signature:

Dennis Daniels, Director Regulatory Affairs