



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

Declaration of Conformity

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
M5073A Adult Training Pads Kit
M5074A Infant/Child Training Pads Kit
M5075A Standard Carrying Case
M5076A Slim Carrying Case
M5089A External Manikin Adapter
M5093A Replacement Adult Training Pads
M5094A Replacement Infant/Child Training Pads
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