Declaration of Conformity

PHILIPS

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
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