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 FRx Model – 861304
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# B12G-02761, August 7, 2012

Product Options/Accessories:

M5070A	Primary Battery
989803139301	Aviation Battery
989803139261	HeartStart SMART Pads II
989803158211	HeartStart DP Pads (1 set)
989803158221	HeartStart DP Pads (5 sets)
989803139311	Infant/Child Key
861487	HeartStart Configure
989803139251	Hard-shell Carrying Case
YC	Standard Carrying Case
989803139271	HeartStart Training Pads II Training Kit
989803139291	Replacement Training Pads II
989803150181	Replacement Training Pads III
989803150201	Replacement Training Pads III Interconnect Cable
M5090A	Adult Pads Placement Guide
989803139281	Infant/Child Pads Placement Guide

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