



DECLARATION OF CONFORMITY

PHILIPS

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

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Name:

HEARTSTART HS1
HEARTSTART FRx
HEARTSTART FR3

Product Model Number or Designator:

HS1 Models M5066A / M5068A: A14B-00001
FRx Models 861304: B14B-00001
FR3 Models 861388 / 861389: C14B-00001

Including the Product Modules/Options/Accessories:

HEARTSTART Pads Adapter Model 05-10000
HEARTSTART Pads Adapter Model 05-10100
HEARTSTART Pads Adapter Model 05-10200
HEARTSTART DP2 AED Defibrillation Pads 989803158211
HEARTSTART DP6 AED Defibrillation Pads 989803158221
FR2 Infant/Child Reduced Energy Defibrillation Pads M3870A
HEARTSTART HS1 Adult Pads Cartridge Models M5071A
HEARTSTART HS1 Infant/Child Pads Cartridge Models M5072A
HEARTSTART SMART Pads II 989803139261
HEARTSTART SMART Pads III 989803149981 (1 pack)
HEARTSTART SMART Pads III 989803149991 (5 pack)
Bluetooth Transceiver Module 989803150081
CPR Meter with Q-CPR® Technology 989803149941
Cable Link 989803149951
3-Lead ECG Cable (IEC) 989803150051
3-Lead ECG Cable (AAMI) 989803150041
Battery Charger 861394
ACT-IR Data Cable
USB Bluetooth Dongle 861488
Defibrillator Cabinet, Basic 989803136531
Defibrillator Cabinet, Blank, Basic 989803169181

The object of the declaration described above is in conformity with:

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Name/Address of Authorized EU Representative:

Philips Medizin Systeme Böblingen GmbH,
Hewlett-Packard Strasse 2
71034 Böblingen
Germany

Additional Information:

The products listed above are fully compliant with the standards listed below:
- EN 50581:2012

Signature (signed for and on behalf of Philips):

Printed Name: John Pardo
Title: Director, Regulatory Affairs

Date of Issue: 01 July 2015

Place of Issue: Bothell, WA