PHILIPS

CONFIDENTIAL

Declaration of Conformity
HeartStart FRx
Models 861304/861305

H05023 Rev F

Prepared By:

Patti Beauregard 7/6/11

Patti Beauregard, Regulatory Affairs Specialist — Date

PHILIPS

Declaration of Conformity

Manufacturer:	Philips Medical Systems 2301 Fifth Avenue, Suite 200 Seattle, WA 98121-1825 USA
European Representative:	Philips Medizin Systeme Boeblingen GmbH Hewlett-Packard Str. 2 71034 Boeblingen Germany
Product:	HeartStart FRx Models – 861304, 861305
Classification:	Class IIb, Rule 9, Annex IX
Conformity Assessment Route:	Annex II

We herewith declare that the above-mentioned products meet the provisions of the council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Notified Body:	TÜV SUD Product Service GmbH Zertifizierstelle Ridlerstrasse 65 D-80339 München Germany
Start of CE-marking:	June 8, 2011 Serial number B11F-00001
UMDNS Code:	17116/Defibrillators, Automatic, External
Place and Date of Issue:	Seattle, WA / July 6, 2010

Signature Tom Trotter, Sr. Manager, Regulatory Affairs — 7/6/2011 Date

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