PHILIPS

CE 0123

DECLARATION OF CONFORMITY

Philips Medical Systems
3000 Minuteman Road
Andover, MA. 01810-1099
USA

Product Name: HeartStart XL+
Product Model Number or Designator: 861290

Control Designator: Serial Number US911XXXXX or higher

Device Classification: *Class 2B, according to Annex IX, Rule 9 of Directive 93/42/EEC*

Global Medical Device Nomenclature Code (GMDN): 33820

Product Options /Accessories:	989803167281	989803147691	M3543A	M4745A
	M5526A	M1783A	M3525A	M3528A
	M3529A			
Product Upgrades:	861395	861396	861397	861401
	861402			

To which this Declaration relates, when shipped, will be in conformity with the provisions of Council Directive: 93/42/EEC (Medical Devices Directive) as amended by 2007/47/EC.

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II-Section 3.2 of the Medical Device Directive. Copies of the certificates are available upon request.

Name/Address of Notified Body: TÜV SÜD- Product Services GmbH, Zertifizierstelle, Ridlerstrasse 65, 80339, MÜNCHEN, GERMANY

Authorized EU Representative: Philips Medizin Systeme Böblingen GmbH, Hewlett-Packard Str. 2, 71034 Böblingen, Germany

Supplementary Information:
The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation. Some accessories which are not medical devices were also tested in the configuration. These are listed below:

989803171261	989803171701	989803171271	989803171291
989803171281	M4759A		

Product upgrade numbers listed above do not change the CE marking status of the product that receives the upgrade. The upgrade by itself is not a finished medical device and therefore does not need to contain the CE mark.

Signature: Mark Puopolo

Printed Name: Mark Puopolo

Title: Sr. Manager, Regulatory Affairs

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