



DECLARATION OF CONFORMITY



ZOLL Medical Corporation
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Chelmsford, MA 01824-4105 USA



ZOLL International Holding B.V.
Newtonweg 18
6662 PV ELST
The Netherlands

Product:

ZOLL AED PRO®

ZOLL declares that the above products conform to European Council Directive 93/42/EEC (Medical Device Directive) Class IIb per rule 9 of Annex IX, assessed per Annex II.

This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

The quality system under which these products were designed and manufactured has been found to be in compliance with the Medical Device Directive including European Standard EN ISO 13485:2012/AC:2012 certified by the notified body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany (Notified Body Number 0123).

The above products are in conformance with the provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which apply to them.

The above products are in conformance with the provisions of Council Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

25 September 2014

Paul Dias
Vice President, QA & RA

Annex to Declaration of Conformity

Accessory List

ZOLL declares that the products listed below conform to European Council Directive 93/42/EEC (Medical Device Directive). Device Classifications are shown next to each product listed as follows: Class I (I), Class I Sterile (IS), Class IIa (IIa), Class IIb (IIb). The MDD Classification Rule used, and the MDD Annex under which the products are assessed, are also indicated.

(X represents any numeric digit)

<u>Accessory</u>	<u>Ref</u>	<u>Class/Rule/Annex</u>
Therapy Electrodes		
Adult, stat ·Padz® II	8900-0801-XX	I / 1 / VII
	8900-0802-XX	I / 1 / VII
Pediatric, pedi ·Padz® II	8900-0810-XX	I / 1 / VII
CPR-D ·Padz	8900-0800-XX	IIb / 9 / II
Batteries and Chargers		
ZOLL SurePower Charger	8050-0030-XX	I / 1 / VII
ZOLL SurePower Single Bay Charger	8200-000100-XX	I / 1 / VII
ZOLL Seal Lead Acid Battery Pack	8000-0299-XX	I / 1 / VII
ZOLL SurePower Battery Pack	8019-0535-XX	I / 1 / VII
ZOLL Non-Rechargeable Battery Pack	8000-0860-XX	I / 1 / VII
Other Accessories		
AAMI 3-Lead ECG Patient Cable	8000-0838	I / 1 / VII
IEC 3-Lead ECG Patient Cable	8000-0839	I / 1 / VII
ECG Electrodes	8900-0003	I / 1 / VII
ECG Simulator	8000-0829-XX	I / 1 / VII
Non-medical device accessories		
Storage Bag	8000-0810-XX	
	8000-0832-XX	
	8000-0875-32	
	8000-0255-01	
USB Cable	8000-000865	
Universal Adapter Cable	8000-0804-XX	
USB IrDA PC Adapter	8000-0815	
RS232 IrDA PC Adapter	8000-0816	
RescueNet® Code Review Software	8000-0608-XX	
ZOLL Administrative Software AEDPro	8000-0843-XX	