



DECLARATION OF CONFORMITY



ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105 USA



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

Product:

ZOLL AED Plus®
ZOLL AED Plus Fully Automatic

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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>	<u>Accessory</u>	<u>Ref</u>	<u>Class/Rule/Annex</u>
Therapy Electrodes			Non-medical device accessories		
Adult, stat •Padz® II	8900-0801-XX	I / 1 / VII	Case (AED Plus)	8000-0802-XX	
	8900-0802-XX	I / 1 / VII		8000-0837-XX	
Pediatric, pEDI •Padz® II	8900-0810-XX	I / 1 / VII		8000-0836-XX	
CPR-D •Padz	8900-0800-XX	IIb / 9 / II		8000-0806-XX	
Battery			Case (AED Plus Trainer)	8000-0375-XX	
Battery, Li-MnO ₂ Type 123A	8000-0807-XX	I / 1 / VII	Universal Adapter Cable	8000-0804-XX	
AED Plus Trainer			USB IrDA PC Adapter	8000-0815	
AED Plus Trainer 2	8008-0050-XX	I / 1 / VII	RS232 IrDA PC Adapter	8000-0816	
AED Plus Fully Automatic			RescueNet® Code Review Software	8000-0608-XX	
Trainer 2	8008-000052-XX	I / 1 / VII	Mounting Bracket	8000-0809-XX	
Other Accessories			Mounting Wall Box	8000-0811	
ECG Simulator	8000-0819-XX	I / 1 / VII		8000-0814	
Device Cover	8000-0812-XX	I / 1 / VII		8000-0817	
	8000-0808-XX	I / 1 / VII		8000-0855-XX	
	8000-0803-XX	I / 1 / VII		8000-0856	
CPR-D padz Training Electrodes	8900-0804-XX	I / 1 / VII		8000-0608-XX	
Replacement Adhesive gels for				8000-0825	
CPR-D padz Training Electrodes	8900-0803-XX	I / 1 / VII		9310-0738	
Pedi-Padz II Training Electrodes	8900-000861-01	I / 1 / VII		8000-0849-XX	
			AC Adapter	8000-0822	
			Trainer Phone Cord	8000-0821	
			Trainer Remote	8000-0822	