



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 3
ZOLL AED 3 Automatic
ZOLL AED 3 BLS

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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

30 March 2016

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)

Defibrillation Pads	REF	Class/Rule/Annex	REF	Class/Rule/Annex
CPR Uni-padz	8900-000260	IIb / 9 / II	8000-001266	Case Wall Mount Bracket
CPR-D padz	8900-0800-01	IIb / 9 / II	8000-001259	Strobe for Standard Surface Wall Cabinet
CPR Stat-padz	8900-0402	IIb / 9 / II	8000-001267	Strobe for Semi/Fully-recessed Wall Cabinet
Stat-padz II	8900-0801-01	I / 1 / VII		
Pedi-padz II	8900-0810-01	I / 1 / VII	8000-001260	ILCOR Flush Wall Sign (AED)
			8000-001261	ILCOR 3D Wall Sign (AED)
Battery			8000-001262	ILCOR Flush Wall Sign (DAE)
AED 3 Battery Pack	8000-000696	I / 1 / VII	8000-001263	ILCOR 3D Wall Sign (DAE)
Simulation/Training			8000-001264	ILCOR Flush Wall Sign (DEA)
Training CPR Uni-padz	8000-000925	I / 1 / VII	8000-001265	ILCOR 3D Wall Sign (DEA)
ZOLL AED Simulator	8900-000264	I / 1 / VII		
Non-medical device accessories				
Battery Case	8000-001251			
Replacement Shoulder Strap	8000-001252			
AED 3 Carry Case	8000-001250			
Small Rigid Plastic Case	8000-001253			
Large Rigid Plastic Case	8000-001254			
Standard Surface Wall Cabinet	8000-001256			
Semi-recessed Wall Cabinet	8000-001257			
Fully-recessed Wall Cabinet	8000-001258			
Device Wall Mount Bracket	8000-001255			