

DECLARATION OF CONFORMITY



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

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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

REF	Class/Rule/Annex		REF	Class/Rule/Annex
8900-000260	IIb / 9 / II	Case Wall Mount Bracket	8000-001266	
8900-0800-01	b / 9 /	Strobe for Standard Surface Wall Cabinet	8000-001259	
8900-0402	IIb / 9 / II	Strobe for Semi/Fully-recessed Wall Cabinet	8000-001267	
8900-0801-01	I/1/VII			
8900-0810-01	/ 1 / VII	ILCOR Flush Wall Sign (AED)	8000-001260	
		ILCOR 3D Wall Sign (AED)	8000-001261	
		ILCOR Flush Wall Sign (DAE)	8000-001262	
8000-000696	/ 1 / V	ILCOR 3D Wall Sign (DAE)	8000-001263	
		ILCOR Flush Wall Sign (DEA)	8000-001264	
Simulation/Training		ILCOR 3D Wall Sign (DEA)	8000-001265	
8000-000925	/ 1 / VI I			
8900-000264	/ 1 / VII			
	8900-000260 8900-0800-01 8900-0402 8900-0801-01 8900-0810-01 8000-000696	8900-000260	Strobe for Standard Surface Strobe for Standard Surface Wall Cabinet	8900-000260 IIb / 9 / II Case Wall Mount Bracket 8000-001266 8900-0800-01 IIb / 9 / II Strobe for Standard Surface Wall Cabinet 8900-0402 IIb / 9 / II Strobe for Semi/Fully-recessed 8000-001267 8900-0801-01 I / 1 / VII Wall Cabinet 8900-0810-01 I / 1 / VII ILCOR Flush Wall Sign (AED) 8000-001260 ILCOR 3D Wall Sign (AED) 8000-001261 ILCOR Flush Wall Sign (DAE) 8000-001262 8000-000696 I / 1 / VII ILCOR 3D Wall Sign (DAE) 8000-001263 ILCOR Flush Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265 8000-000925 I / 1 / VII ILCOR 3D Wall Sign (DEA) 8000-001265

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