



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® - see attached catalog list
ZOLL AED Plus Fully Automatic - see attached catalog list

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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 were in conformance with the provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE). At this time the above products are in conformance with the provisions of Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

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.

Elizabeth McMeniman

September 25, 2018

Date

Associate Director, Regulatory Affairs

20000000100011020	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, FRENCH
20000000100011100	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, SPANISH
20000000300011070	MAIN ASSY, PS SERIES, NO GRAPHICS, LCD, NO VOICE RCDG, 50HZ, UK (PROPER)
20100000101011020	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, FRENCH, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, FRENCH
20100000101011050	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, UK
20100000101011080	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, GERMAN, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, GERMAN, ZOLL AED Plus, "Public Safety" Serie, mit graphischem Cover
20100000101011100	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, ERC, SPANISH, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, SPANISH
20100000101011110	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, ITALIAN, AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, ITALIAN
20100000101011160	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RECORDING, 50HZ, DUTCH, ZOLL AED Plus, PS Serie, grafische deksel, zonder stemopname optie
20100000101011180	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, PORTUGUESE
20100000101011210	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, 50HZ, FINNISH
20100000101011280	AED PLUS, PS SERIES, W/PA CVR, LCD, NO VOICE RCDG, INTERNATIONAL AHA ENGLISH
20100000102011010	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, ENGLISH
20100000102011020	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, FRENCH, AED Plus, Semi-Automatique, Interface avec pictogramme, FR, Défibrillateur ZOLL AED Plus semi-automatique - interface pictogrammes, ZOLL "Public Safety" Serie AED Plus, französisch
20100000102011050	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, UK, ZOLL AED Plus, PS Serie, zonder stemopname optie, Engels, ZOLL AED Plus, PS Series, English, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RCDG, UK
20100000102011070	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, UK (PROPER)
20100000102011080	AED Plus senza Registrazione Audio Ambientale e con coperchio AED in lingua tedesca, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, GERMAN, ZOLL "Public Safety" Serie AED Plus, ZOLL AED Plus, PS Serie, zonder stemopname optie, Duits
20100000102011090	AED PLUS, PS SERIES, W/AED CVR. LCD, NO VOICE RCDG, AHA, SWITZERLAND/GERMAN
20100000102011100	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, ERC, SPANISH, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, SPANISH
20100000102011110	AED Plus senza Registrazione Audio Ambientale e con coperchio AED, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, ITALIAN, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, ITALIAN
20100000102011160	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, DUTCH, ZOLL AED Plus, PS Serie, zonder stemopname optie, Nederlands, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, NEDERLANDS
20100000102011180	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, PORTUGUESE, ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RECORDING, PORTUGUESE

20100000102011210	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, FINNISH
20100000102011280	AED PLUS, PS SERIES, LCD, NO VOICE RCDG, INTERNATIONAL AHA ENGLISH, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, INTERNATIONAL AHA ENGLISH
20100000102011410	AED Plus con coperchio AED, no reg. audio. Linee guida AHA, AED PLUS, PS SERIES, LCD, NO VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20100000102011550	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, TURK
20100000302011050	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, UK, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, UK
20100000302011070	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, UK (PROPER)
20100001101011100	AED PLUS, PS SERIES W/BASIC CVR, LCD, VOICE RCDG, 50 HZ SPANISH, AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, ERC, SPANISH
20100001102011020	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, FRENCH
20100001302011410	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20100010102011320	ZOLL AED PLUS, PS SERIES, LCD, NO VOICE RCDG, W/BATTERIES, FED GOVT VALUE PKG
20100800101011050	AED PLUS, PS SERIES, W/PA CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, UK
20100800102011080	AED PLUS, PS SERIES, ECG ON, LCD, NO VOICE RCDG, GERMAN, AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, GERMAN
20100800102011110	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, ITALIAN
20100800102011410	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20100800302011070	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, UK (PROPER)
20200000101011040	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, POLISH
20200000101011170	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, CZECH
20200000101011200	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, NORWEGIAN, AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RECORDING, 50HZ, NORWEGIAN
20200000101011220	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH
20200000101011270	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20200000101011290	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, RUSSIAN
20200000101011340	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, ARABIC
20200000101011450	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, HUNGARIAN
20200000101011520	AED PLUS, PS SERIES, BASIC CVR, LCD, NO VOICE RCDG, CROATIAN, 50HZ
20200000101011530	AED PLUS, PS SERIES, BASIC CVR, LCD, NO VOICE RCDG, SLOVENIAN
20200000101011550	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, TURK
20200000102011040	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, POLISH
20200000102011130	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, AUS, 50HZ
20200000102011170	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, 50HG, CZECH
20200000102011190	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, GREEK

20200000102011200	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, NORWEGIAN, ZOLL AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDNG, 50HZ, NORWEGIAN
20200000102011220	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH, AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH
20200000102011270	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20200000102011290	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, RUSSIAN
20200000102011330	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, THAI, 50HZ
20200000102011520	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, CROATIAN, 50HZ
20200000102019050	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, AIRLINE, UK
20200000102019080	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, AIRLINE, GERMAN
20200000302011020	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, FRENCH, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, FRENCH
20200000302011080	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, GERMAN
20200000302011160	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH
20200000302011210	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, FINNISH
20200000303011050	AED PLUS, PS SERIES, W/LOW PROFILE CVR, LCD, NO VOICE RCDG, 50HZ, UK
20200001101011020	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, FRENCH, ZOLL AEDPlus Interface Pictogramme/Couvercle PS avec enregistrement vocal
20200001101011050	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, 50HZ, UK
20200001101011080	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, GERMAN, ZOLL AED Plus "Public Safety", mit Sprachaufzeichnung
20200001101011100	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, ERC, SPANISH
20200001101011110	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, ITALIAN
20200001101011170	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, 50HZ, CZECH
20200001101011180	AED PLUS, PS SERIES, W/BASIC CVR, LCD, VOICE RCDG, 50HZ, PORTUGUESE
20200001101011290	AED PLUS, PS SERIES W/BASIC CVR, LCD, VOICE RCDG, 50HZ, RUSSIAN
20200001101011530	AED PLUS, PS SERIES W/BASIC CVR, LCD, VOICE RCDG, 50HZ, SLOVENIAN
20200001102011110	AED Plus con Registrazione Audio Ambientale e con coperchio AED, AED PLUS, PS SERIES, W/AED CVR, LCD, VOICE RCDG, ITALIAN
20200001102011410	AED PLUS, PS SERIES W/AED CVR, LCD, VOICE RCDG, AHA, SWITZERLAND/ITALIAN
20200001302011020	AED PLUS, PS SERIES NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, FRENCH, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, FRENCH, Défibrillateur ZOLL AED Plus semi-automatique - Interface Professionnelle avec enregistrement de l'ambiance sonore
20200001302011110	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, VOICE RCDG, ITALIAN
20200800101011290	AED PLUS, PS SERIES, AED CVR, ECG ON, LCD, NO VOICE RCDG, RUSSIAN
20200800102011040	AED PLUS, PS SERIES, AED CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, POLISH

20200800102019080	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, AIRLINE, GERMAN
20200800302011080	AED PLUS, PS SERIES, AED CVR, ECG ON, LCD, NO VOICE RCDG, 50HZ, GERMAN
20300000101011200	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, NORWEGIAN
20300000101011210	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, FINNISH
20300000101011220	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, SWEDISH
20300000101011270	AED PLUS, PS SERIES, W/BASIC CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20300000102011050	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, 50HZ, DUTCH ARMY
20300000102011070	AED PLUS, PS SERIES, W/AED CVR, NO CARRY CASE, LCD, NO VOICE RCDG, UK (PROPER)
20300000102011160	AED PLUS, PS SERIES, AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY, AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY, AED Plus, semi-automatische defibrillator, NL Leger, NL
20300000102011210	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, FINNISH
20300000102011270	AED PLUS, PS SERIES, W/AED CVR, LCD, NO VOICE RCDG, 50HZ, DANISH
20300000302011050	AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY
20300000302011160	AED PLUS, PS SERIES, NO GRAPHICS, AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY, AED PLUS, PS SERIES, NO GRAPHICS, W/AED CVR, LCD, NO VOICE RCDG, DUTCH ARMY
20300800102011080	AED PLUS, PS SERIES, W/AED CVR, ECG ON, LCD, NO VOICE RCDG, GERMAN
20400000001000020	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, FRENCH
20400000001000080	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, GERMAN, ZOLL"Public Safety" Serie AED Plus, Foundation-Modell
20400000001000160	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, DUTCH
20400000001000180	AED PLUS, PA SERIES, W/BASIC CVR, NO LCD, NO VOICE RCDG, PORTUGUESE
21400710702011010	AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, 60HZ, ENG
22300700502011050	AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, UK
22300700502011080	AED PLUS, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, GERMAN
22300700502011160	AED PLUS, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, DUTCH
22300700702011280	AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, AHA, INTL ENGLISH, AED PLUS, PS SERIES, FULLY AUTOMATIC, W/AED CVR, LCD, NO VOICE RCDG, INTL ENGLISH
22300703502011020	AED Plus, Entièrement Automatique, Interface avec pictogramme, FR, AED PLUS, PS SERIES, FULLY AUTOMATIC, LCD, NO VOICE RCDG, FRENCH, Défibrillateur ZOLL AED Plus entièrement automatique - interface pictogrammes
23000010102011320	AED PLUS, PS SERIES, LCD, NO VOICE RCDG, W/BATTERIES, MIL W/O WALL CAB
23100010102011320	AED PLUS, PS SERIES, LCD NO VOICE RCDG, W/BATTERIES, MIL W/WALL CAB
25100060310011070	AED PLUS, PS SERIES, LCD, NO VOICE RCDG, UK ENGLISH, AVIATION

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	Case (AED Plus Trainer)	8000-0806-XX	
			Universal Adapter Cable	8000-0375-XX	
			USB IrDA PC Adapter	8000-0804-XX	
Battery			RS232 IrDA PC Adapter	8000-0815	
Battery, Li-MnO ₂ Type 123A	8000-0807-XX	I / 1 / VII	RescueNet® Code Review Software	8000-0816	
			Mounting Bracket	8000-0608-XX	
AED Plus Trainer			Mounting Wall Box	8000-0809-XX	
AED Plus Trainer 2	8008-0050-XX	I / 1 / VII		8000-0811	
AED Plus Fully Automatic				8000-0814	
Trainer 2	8008-000052-XX	I / 1 / VII		8000-0817	
				8000-0855-XX	
Other Accessories				8000-0856	
Device Cover	8000-0812-XX	I / 1 / VII	Sign, AED	8000-0608-XX	
	8000-0808-XX	I / 1 / VII		8000-0825	
	8000-0803-XX	I / 1 / VII		9310-0738	
CPR-D padz Training Electrodes	8900-0804-XX	I / 1 / VII	AC Adapter	8000-0849-XX	
Replacement Adhesive gels for			Trainer Phone Cord	8000-0822	
CPR-D padz Training Electrodes	8900-0803-XX	I / 1 / VII	Trainer Remote	8000-0821	
Pedi-Padz II Training Electrodes	8900-000861-01	I / 1 / VII	ECG Simulator	8000-0822	
				8000-0819-XX	