



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
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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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 13485:2016 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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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**

Digitally signed by
Elizabeth McMeniman
Date: 2019.12.10
10:47:16 -05'00'

Elizabeth McMeniman
Director, Regulatory Affairs

December 10, 2019

Date

Catalog Number	Description
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, NETHERLANDS
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

Catalog Number	Description
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 RCRDG, 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

Catalog Number	Description
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

Catalog Number	Description
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
20000000100011070	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, UK (PROPER)

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).

<u>Accessory</u>	REF
Therapy Electrodes	
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01
STAT-PADZ II ADULT MULTI-FUNCTION ELECTRODES (1 PAIR), JAPANESE	8900-0801-36
STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-01
STAT-PADZ II MULTI-FUNCTION ELECTRODES - 12/CASE, BRAZILIAN PORTUGUESE	8900-0802-24
STAT-PADZ II ELECTRODES, 12/CASE, JAPANESE	8900-0802-36
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01
PEDI-PADZ II, AED PLUS, BRAZIL, SINGLES	8900-0810-24
PEDI-PADS II ELECTRODES, JAPAN, SINGLE	8900-0810-36
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01
CPR-D-PADZ ELECTRODES, W/ACCESSORY KIT, BRAZILLIAN PORTUGUESE	8900-0800-24
CPR-D-PADZ ELECTRODES, W/ACCESSORY KIT, JAPAN	8900-0800-36
Battery	
TYPE 123 LITHIUM BATTERIES	8000-0807-01
AED Plus Trainer	
AED Plus Trainer 2	8008-0050-XX
AED Plus Fully Automatic Trainer 2	8008-000052-XX
Other Accessories	
REPLACEMENT PUBLIC SAFETY PASS COVER	8000-0812-01
REPLACEMENT PUBLIC ACCESS PASS COVER (GRAPHIC INTERFACE LABEL)	8000-0808-01
COMPACT LOW PROFILE PUBLIC SAFETY COVER	8000-0803-01
TRAINING CPR-D PADZ ELECTRODE, WITH 1 PAIR REP. GEL	8900-0804-01
TRAINING CPR-D REPLACEMENT GEL 5/CASE	8900-0803-01
PEDI-PADZ II TRAINING ELECTRODES (6/CASE)	8900-000861-01
Non-Medical Device Accessories	
REPLACEMENT SOFTCASE	8000-0802-01
LARGE PELICAN CASE	8000-0837-01
SMALL PELICAN CASE	8000-0836-01
REPLACEMENT SOFTCASE - POLICE	8000-0806-01
KIT SOFTCASE, AED PLUS TRAINER2	8000-0375-01
KIT, CABLE ADAPTER, UNIVERSAL ZOLL AED PLUS	8000-0804-01
USB IRDA ADAPTER	8000-0815
RS-232 IRDA ADAPTER	8000-0816

RESCUENET CODE REVIEW STANDARD SOFTWARE FOR WINDOWS	8000-0608-01
MOUNTING BRACKET	8000-0809-01
FULLY RECESSED WALL MOUNTING CABINET	8000-0811
RECESSED WALL MOUNTING CABINET	8000-0814
SURFACE WALL MOUNTING CABINET	8000-0817
STANDARD METAL WALL CABINET w/ZOLL LOGO	8000-0855
BRUSHED STAINLESS STEEL WALL CABINET	8000-0855-02
CLEAR AED PLUS WALL CABINET	8000-0856
AED WALL SIGN KIT, ONE FLUSH AND ONE 3-D WALL SIGN	8000-0825
AED PLUS 3-D WALL SIGN	9310-0738
KIT, LABEL, DECAL, ZOLL DEFIBRILLATOR EQUIPPED, PK OF 10, AED PLUS	8000-0849-01
TRAINER US AC ADAPTER	8000-0822
TRAINER PHONE CORD (REPLACEMENT)	8000-0821
TRAINER US AC ADAPTER	8000-0822
SIMULATOR / TESTER	8000-0819-XX

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: ZOLL Medical Corporation
Business address: 269 Mill Road
Chelmsford, MA 01824
Medical device(s): See Schedule 2
Classification: See Schedule 2
GMDN code and term: See Schedule 2
Scope of application: All products to which the full quality assurance procedure applies.

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate: No. QS6 079546 0021
No. Q5 079546 0020
No. G1 079546 0023
No. G2S 079546 0022

Standards applied: See Schedule 1

SCHEDULE 1

Conformity Standard	Description of Standard
ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN 60601-1: 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: ed3.0 (2007-03)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-4: 2010	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
IEC 62366: 2014	Medical devices – Application of usability engineering to medical devices
MEDDEV 2.7.1: 2003	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
ISO 10993-1: 2010	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Conformity Standard	Description of Standard
ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971: 2012	Medical devices – Application of risk management to medical devices
EN 60601-1: 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: ed3.0 (2007-03)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
ISO 10993-5: 2010	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10: 2010	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041: 2008	Information supplied by the manufacturer of medical devices

SCHEDULE 2

Catalog Number	Description	GMDN Code
20000000100011010	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, ENGLISH	47910
20000000100011050	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, UK	47910
20000000100011130	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, AUS	47910
20000000100011230	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 60HZ, SPANISH	47910
20000000100011330	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, 50HZ, THAI	47910
20000000100011590	MAIN ASSY, PS SERIES, LCD, NO VOICE RCDG, SINGAPORE	47910
20000001100011050	MAIN ASSY, PS SERIES, LCD, VOICE RCDG, 50HZ, UK	47910
20000700500011130	MAIN ASSY, FULLY AUTOMATIC, PS SERIES, LCD, NO VOICE RCDG, 50HZ, AUS	48047
70000000102011130	MAIN ASSY, PS SERIES, W/AED CVR, LCD, NO VOICE RECORDING, AUS/NZ, REFURB	47910

Accessory Description	Accessory Catalog Number	GMDN Code
Therapy Electrodes		
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01	15033
STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-01	15033
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01	15033
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01	15033
Battery		
TYPE 123 LITHIUM BATTERIES	8000-0807-01	35848

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Non-Medical Device Accessories	
AED Plus Trainer 2	8008-0050-XX
AED Plus Fully Automatic Trainer 2	8008-000052-XX
REPLACEMENT PUBLIC SAFETY PASS COVER	8000-0812-01
REPLACEMENT PUBLIC ACCESS PASS COVER (GRAPHIC INTERFACE LABEL)	8000-0808-01
COMPACT LOW PROFILE PUBLIC SAFETY COVER	8000-0803-01
TRAINING CPR-D PADZ ELECTRODE, WITH 1 PAIR REP. GEL	8900-0804-01
TRAINING CPR-D REPLACEMENT GEL 5/CASE	8900-0803-01
PEDI-PADZ II TRAINING ELECTRODES (6/CASE)	8900-000861-01
REPLACEMENT SOFTCASE	8000-0802-01
LARGE PELICAN CASE	8000-0837-01
SMALL PELICAN CASE	8000-0836-01
REPLACEMENT SOFTCASE - POLICE	8000-0806-01
KIT SOFTCASE, AED PLUS TRAINER2	8000-0375-01
KIT, CABLE ADAPTER, UNIVERSAL ZOLL AED PLUS	8000-0804-01
USB IRDA ADAPTER	8000-0815
RS-232 IRDA ADAPTER	8000-0816
RESCUENET CODE REVIEW STANDARD SOFTWARE FOR WINDOWS	8000-0608-01
MOUNTING BRACKET	8000-0809-01
FULLY RECESSED WALL MOUNTING CABINET	8000-0811
RECESSED WALL MOUNTING CABINET	8000-0814
SURFACE WALL MOUNTING CABINET	8000-0817
STANDARD METAL WALL CABINET w/ZOLL LOGO	8000-0855
BRUSHED STAINLESS STEEL WALL CABINET	8000-0855-02
CLEAR AED PLUS WALL CABINET	8000-0856
AED WALL SIGN KIT, ONE FLUSH AND ONE 3-D WALL SIGN	8000-0825
AED PLUS 3-D WALL SIGN	9310-0738
KIT, LABEL, DECAL, ZOLL DEFIBRILLATOR EQUIPPED, PK OF 10, AED PLUS	8000-0849-01
TRAINER US AC ADAPTER	8000-0822
TRAINER PHONE CORD (REPLACEMENT)	8000-0821
TRAINER US AC ADAPTER	8000-0822
SIMULATOR / TESTER	8000-0819-XX

Authorised signatory:

Elizabeth
McMeniman

Digitally signed by
Elizabeth McMeniman
Date: 2019.12.10 10:47:47
+05'00'

Signature

Elizabeth McMeniman, Director, Regulatory Affairs

Name, Position

December 10, 2019

Date