



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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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

March 20, 2019

Date

Catalog Number	Description
90110200499991010	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO BATTERY, NO ELECTRODES
90110340499991010	AED PRO, SEMI-AUTO/MANUAL, (1 CPR-D PAD), CARRY CASE
90110600499991010	AED PRO, MANUAL ONLY, NO VOICE, LCD, ENGLISH
90210200499991010	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, ENGLISH
90210200499991020	AED PRO, SEMI AUTO W/MNL OVERRIDE, FRENCH
90210200499991040	AED PRO, SEMI AUTO W/MNL OVERRIDE, POLISH
90210200499991050	AED PRO, SEMI AUTO W/MNL OVERRIDE, 50HZ, UK
90210200499991070	AED PRO, SEMI AUTO W/MNL OVERRIDE, 50HZ, UK (PROPER)
90210200499991080	AED PRO, SEMI AUTO W/MNL OVERRIDE, GERMAN
90210200499991100	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50 HZ SPANISH
90210200499991110	AED PRO, SEMI AUTO W/MNL OVERRIDE, ITALIAN
90210200499991160	AED PRO, SEMI AUTO W/MNL OVERRIDE, DUTCH
90210200499991170	AED PRO, SEMI-AUTO/MANUAL OVERRIDE, 50HZ, CZECH
90210200499991180	AED PRO, SEMI-AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50HZ, IBERIAN PORTUGUESE
90210200499991200	AED PRO, SEMI AUTO W/MNL OVERRIDE, NORWEGIAN
90210200499991210	AED PRO, SEMI AUTO W/MNL OVERRIDE, FINNISH
90210200499991220	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO BATTERY, NO VOICE, LCD, SWEDISH
90210200499991230	AED PRO, SEMI AUTO W/MNL OVERRIDE, SPANISH
90210200499991240	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 60 HZ PORTUGUESE
90210200499991270	AED PRO, SEMI AUTO W/MNL OVERRIDE, DANISH
90210200499991280	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50HZ, AHA, INTERNATIONAL ENGLISH
90210200499991290	AED PRO, SEMI AUTO W/MNL OVERRIDE, RUSSIAN
90210200499991410	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50HZ, AHA, SWITZERLAND/ITALIAN
90210200499991530	AED PRO, SEMI AUTO W/MNL OVERRIDE, SLOVENIAN
90210202499991020	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, FRENCH
90210202499991050	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, UK
90210202499991080	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, GERMAN
90210202499991110	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, GERMAN
90210202499991160	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, DUTCH
90210220499991020	NOT FOR CLINICAL USE, AED PRO, SEMI AUTO W/MNL OVERRIDE, FRENCH
90210220499991050	AED PRO, SEMI AUTO W/MNL OVERRIDE, 50HZ, UK
90210220499991080	NOT FOR CLINICAL USE, AED PRO, SEMI AUTO W/MNL OVERRIDE, GERMAN
90210220499991210	AED PRO, SEMI AUTO W/MNL OVERRIDE, FINNISH
90210400499991020	AED PRO, SEMI-AUTO ONLY, NO BATTERY, NO VOICE, FRENCH, W/CARRY CASE
90210400499991050	AED PRO, SEMI-AUTO ONLY, 50HZ, UK, W/ CARRY CASE
90210400499991070	AED PRO, SEMI-AUTO ONLY, 50HZ, W/ CARRY CASE, UK (PROPER)
90210400499991080	AED PRO, SEMI-AUTO ONLY, NO BATTERY, NO VOICE, GERMAN, W/CARRY CASE
90210400499991110	AED PRO, SEMI-AUTO ONLY, NO BATTERY, NO VOICE, ITALIAN, W/CARRY CASE
90210400499991160	AED PRO, SEMI-AUTO ONLY, NO BATTERY, NO VOICE, DUTCH, W/CARRY CASE
90210400499991270	AED PRO, SEMI-AUTO ONLY, NO BATTERY, NO VOICE, DANISH
90210402499991080	AED PRO, SEMI AUTO ONLY, AUDIO RECORDING, GERMAN
90210402499991230	AED PRO, SEMI AUTO ONLY, AUDIO RECORDING, SPANISH
90210600499991020	AED PRO, MANUAL ONLY, NO VOICE, LCD, FRENCH
90210600499991130	AED PRO, MANUAL ONLY, NO VOICE, LCD, AUSTRALIA
90210600499991270	AED PRO, MANUAL ONLY, NO VOICE, LCD, DANISH
93010340499991010	AED PRO, SEMI-AUTO/MANUAL, (1 CPR-D PAD), CARRY CASE

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>
Defibrillation Accessories		
STAT-PADZ II ELECTRODE	8900-0801-XX	I / 1 / VII
STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-XX	I / 1 / VII
PEDI-PADZ II ELECTRODES	8900-0810-XX	I / 1 / VII
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-XX	IIb / 9 / II
Power Accessories		
SUREPOWER CHARGING STATION	8050-0030-XX	I / 1 / VII
SINGLE BAY CHARGER	8200-000100-XX	I / 1 / VII
BATTERY, LEAD ACID	8000-0299-XX	I / 1 / VII
SUREPOWER* RECHARGEABLE LITHIUM ION BATTERY PACK	8019-0535-XX	I / 1 / VII
AED PRO NON-RECHARGEABLE LITHIUM BATTERY PACK	8000-0860-XX	I / 1 / VII
Other Accessories		
AED PRO ECG CABLE AAMI	8000-0838	I / 1 / VII
CABLE, 3-LEAD ECG, IEC, AED PRO	8000-0839	I / 1 / VII
3 ECG RECTANGULAR ELECTRODES, 20 SHELF CARTONS / CASE (600)	8900-0003	I / 1 / VII
Non-Medical Device Accessories		
AED PRO SOFT CARRY CASE	8000-0810-XX	
AED PRO MOLDED VINYL CARRY CASE WITH SPARE BATTERY COMPARTMENT	8000-0832-XX	
AED PRO HARD CASE WITH FOAM CUT-OUTS (PELICAN)	8000-0875-32	
BAG, COMBINATION AED PRO/PROPAQ LT	8000-0255-01	
USB CLINICAL EVENT DOWNLOAD CABLE	8000-000865	
KIT, CABLE ADAPTER, UNIVERSAL ZOLL AED PLUS	8000-0804-XX	
USB IRDA ADAPTER	8000-0815	
RS-232 IRDA ADAPTER	8000-0816	
ZOLL RESCUENET CODE REVIEW	8000-0608-XX	
CD-ROM, ZOLL ADMINISTRATION SOFTWARE (ZAS), AED PRO	8000-0843-XX	
AED PRO SIMULATOR	8000-0829-XX	

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCTION QUALITY ASSURANCE PROCEDURES

This is a declaration of conformity made under clause 4.7 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
Classification: Class IIb
GMDN code and term: 48048 – Rechargeable professional automated external defibrillator
45806 – Multifunction cardiac electrode, adult
42404 – Multifunction cardiac electrode, paediatric
17115 – External device battery charger
36534 – Rechargeable battery pack
42489 – Electrocardiographic electrode, reusable
35035 – Electrocardiographic electrode, single-use
48058 – Disposable battery pack
Scope of application: ZOLL AED PRO® - See attached catalog list and accessories

For each kind of medical device to which the production quality assurance procedures have been applied the type examination procedures have also been applied to the kind of device. The kind of device has been shown to conform to the approved type and that each kind of medical devices to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules and the production quality assurance procedures before being supplied.

Production quality assurance procedures certificate: *No. QS6 079546 0021*
No. Q5 079546 0020

Type examination certificate: *No. G1 16 06 79546 016*
No. G2S 16 02 79546 014

Standards applied:

Conformity Standard	Description of Standard
ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971: 2007	Medical devices – Application of risk management to medical devices
EN 1041: 2008	Information supplied by the manufacturer of medical devices
IEC 60601-1: 2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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Conformity Standard	Description of Standard
IEC 62366: 2014	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-4: 2012	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
MEDDEV 2.7.1: 2003	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
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 (ISO 15223-1:2016, Corrected version 2017-03)

ZOLL AED PRO® - CATALOG LIST AND ACCESSORIES

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AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

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STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-XX
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Power Accessories	
SUREPOWER CHARGING STATION	8050-0030-XX
SINGLE BAY CHARGER	8200-000100-XX
BATTERY, LEAD ACID	8000-0299-XX
SUREPOWER* RECHARGEABLE LITHIUM ION BATTERY PACK	8019-0535-XX
AED PRO NON-RECHARGEABLE LITHIUM BATTERY PACK	8000-0860-XX
Other Accessories	
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CABLE, 3-LEAD ECG, IEC, AED PRO	8000-0839
3 ECG RECTANGULAR ELECTRODES, 20 SHELF CARTONS / CASE (600)	8900-0003
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USB CLINICAL EVENT DOWNLOAD CABLE	8000-000865
KIT, CABLE ADAPTER, UNIVERSAL ZOLL AED PLUS	8000-0804-XX
USB IRDA ADAPTER	8000-0815
RS-232 IRDA ADAPTER	8000-0816
ZOLL RESCUENET CODE REVIEW	8000-0608-XX
CD-ROM, ZOLL ADMINISTRATION SOFTWARE (ZAS), AED PRO	8000-0843-XX
AED PRO SIMULATOR	8000-0829-XX



Signature

Elizabeth McMeniman, Associate Director, Regulatory Affairs

Name, Position

March 20, 2019

Date