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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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

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Date: 2021.02.23 13:01:20 -05'00'

Elizabeth McMeniman
Director, Regulatory Affairs

Digitally signed by Ceaicovschi Tudor
Date: 2021.06.29 17:49:19 EEST
Reason: MoldSign Signature
Location: Moldova

February 23, 2021
Date

Catalog Number	Description
90110200499991010	AED PRO, SEMI AUTO W/MNL OVERIDE, 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 OVERIDE, FRENCH
90210200499991040	AED PRO, SEMI AUTO W/MNL OVERIDE, POLISH
90210200499991050	AED PRO, SEMI AUTO W/MNL OVERIDE, 50HZ, UK
90210200499991070	AED PRO, SEMI AUTO W/MNL OVERIDE, 50HZ, UK (PROPER)
90210200499991080	AED PRO, SEMI AUTO W/MNL OVERIDE, GERMAN
90210200499991100	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50 HZ SPANISH
90210200499991110	AED PRO, SEMI AUTO W/MNL OVERIDE, ITALIAN
90210200499991160	AED PRO, SEMI AUTO W/MNL OVERIDE, 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 OVERIDE, NORWEGIAN
90210200499991210	AED PRO, SEMI AUTO W/MNL OVERIDE, FINNISH
90210200499991220	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO BATTERY, NO VOICE, LCD, SWEDISH
90210200499991230	AED PRO, SEMI AUTO W/MNL OVERIDE, SPANISH
90210200499991240	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 60 HZ PORTUGUESE
90210200499991270	AED PRO, SEMI AUTO W/MNL OVERIDE, DANISH
90210200499991280	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50HZ, AHA, INTERNATIONAL ENGLISH
90210200499991290	AED PRO, SEMI AUTO W/MNL OVERIDE, RUSSIAN
90210200499991410	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50HZ, AHA, SWITZERLAND/ITALIAN
90210200499991530	AED PRO, SEMI AUTO W/MNL OVERIDE, 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 CLINICALUSE,AED PRO, SEMI AUTO W/MNL OVERIDE, FRENCH
90210220499991050	AED PRO, SEMI AUTO W/MNL OVERIDE, 50HZ, UK
90210220499991080	NOT FOR CLINICAL USE,AED PRO, SEMI AUTO W/MNL OVERIDE, GERMAN
90210220499991210	AED PRO, SEMI AUTO W/MNL OVERIDE, 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, GERMEN
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).

Accessory	REF
Defibrillation Accessories	
STAT-PADZ II ELECTRODE	8900-0801-XX
STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-XX
PEDI-PADZ II ELECTRODES	8900-0810-XX
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-XX
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	
AED PRO ECG CABLE AAMI	8000-0838
CABLE, 3-LEAD ECG, IEC, AED PRO	8000-0839
3 ECG RECTANGULAR ELECTRODES, 20 SHELF CARTONS / CASE (600)	8900-0003
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 079546 0025** **No. G2S 079546 0022**

Standards applied:

Conformity Standard	**Description of Standard**
ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971: 2019	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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AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCTION QUALITY ASSURANCE PROCEDURES

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

Catalog Number	Description
90110200499991010	AED PRO, SEMI AUTO W/MNL OVERIDE, 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 OVERIDE, FRENCH
90210200499991040	AED PRO, SEMI AUTO W/MNL OVERIDE, POLISH
90210200499991050	AED PRO, SEMI AUTO W/MNL OVERIDE, 50HZ, UK
90210200499991070	AED PRO, SEMI AUTO W/MNL OVERIDE, 50HZ, UK (PROPER)
90210200499991080	AED PRO, SEMI AUTO W/MNL OVERIDE, GERMAN
90210200499991100	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 50 HZ SPANISH
90210200499991110	AED PRO, SEMI AUTO W/MNL OVERIDE, ITALIAN
90210200499991160	AED PRO, SEMI AUTO W/MNL OVERIDE, DUTCH
90210200499991170	AED PRO, SEMI-AUTO/MANUAL OVERRIDE, 50HZ, CZECH
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90210200499991220	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO BATTERY, NO VOICE, LCD, SWEDISH
90210200499991230	AED PRO, SEMI AUTO W/MNL OVERIDE, SPANISH
90210200499991240	AED PRO, SEMI AUTO W/MNL OVERRIDE, NO VOICE, LCD, 60 HZ PORTUGUESE
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90210202499991050	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, UK
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90210202499991110	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, GERMAN
90210202499991160	AED PRO, SEMI-AUTO W/MNL OVERRIDE, VOICE, DUTCH
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MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCTION QUALITY ASSURANCE PROCEDURES

Catalog Number	Description
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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, GERMEN
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Accessory Description	**Accessory Catalog Number** (X represents any numeric digit)
Defibrillation Accessories	
STAT-PADZ II ELECTRODE	8900-0801-XX
STAT-PADZ II ELECTRODE, 12/CASE	8900-0802-XX
PEDI-PADZ II ELECTRODES	8900-0810-XX
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-XX
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	
AED PRO ECG CABLE AAMI	8000-0838
CABLE, 3-LEAD ECG, IEC, AED PRO	8000-0839
3 ECG RECTANGULAR ELECTRODES, 20 SHELF CARTONS / CASE (600)	8900-0003
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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

Elizabeth McMeniman

Digitally signed by Elizabeth McMeniman
Date: 2021.02.23 13:00:48 -05'00'

Signature

Elizabeth McMeniman, Director, Regulatory Affairs _ Name, Position

Chelmsford, MA USA

February 23, 2021

Date