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

ZOLL Medical Switzerland A.G.
Bahnhofstrasse 20
6300, Zug
Switzerland

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 and Switzerland's Medical Device Ordinance (MedDO) of 1 July 2020.

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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 as amended by Council Directive (EU) 2017/2102 on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

Natalie England

Digitally signed by Natalie England
Date: 2021.12.10 10:06:50 Z

Name: Natalie England Date
Position: Regulatory Affairs Manager
Location: Chelmsford, MA USA

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

Class IIb Battery Accessories	
BATTERY, LEAD ACID	8000-0299-XX
AED PRO NON-RECHARGEABLE LITHIUM BATTERY PACK	8000-0860-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.

REF

Manufacturer's name:	ZOLL Medical Corporation
Business address:	269 Mill Road Chelmsford, MA 01824 USA
Medical device(s)	ZOLL AED Pro® - see attached catalog list
Classification:	Class IIb
GMDN code and term:	48048 – Rechargeable professional automated external defibrillator 48058 – Disposable battery pack
Scope of application:	All devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn

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 (MDSAP Certificate)**
No. Q5 079546 0029 (ISO 13485 Certificate)
No. G1 079546 0028 (EC Certificate)

Design examination certificate (if applicable): ***N/A***

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
ISO 20417:2021	Medical devices. Information supplied by the manufacturer.
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
IEC 62366: 2014	Medical devices – Application of usability engineering to medical devices

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AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

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Conformity Standard	Description of Standard
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: 2016	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
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

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Catalog Number	Description
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

Accessory Description	Accessory Catalog Number (X represents any numeric digit)
Power Accessories	
BATTERY, LEAD ACID	8000-0299-XX
AED PRO NON-RECHARGEABLE LITHIUM BATTERY PACK	8000-0860-XX

Authorized signatory:

Natalie England Digitally signed by Natalie England
Date: 2021.12.10 10:07:39 Z

Natalie England
Regulatory Affairs Manager

Date