



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 3
ZOLL AED 3 Automatic
ZOLL AED 3 BLS
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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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.

Name: Elizabeth McMeniman
Position: Director, Regulatory Affairs
Location: Chelmsford, MA USA

December 8, 2020
Date

Catalog Number	Description
8501-001101-06	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8501-001101-26	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH CANADIAN, AHA
8501-001102-06	AUTOMATIC, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8501-001102-26	AUTOMATIC, ZOLL AED 3, FRENCH CANADIAN, AHA
8502-001103-06	BLS, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8502-001103-26	BLS, ZOLL AED 3, FRENCH CANADIAN, AHA
8503-001103-06	BLS, W/O CARRY CASE, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8503-001103-26	BLS, W/O CARRY CASE, ZOLL AED 3, FRENCH CANADIAN, AHA
8501-001201-07	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8501-001201-12	SEMI-AUTOMATIC, ZOLL AED 3, INTL ENGLISH ERC
8501-001201-23	SEMI-AUTOMATIC, ZOLL AED 3, SPANISH AHA
8501-001202-23	AUTOMATIC, ZOLL AED 3, SPANISH AHA
8501-001202-28	AUTOMATIC, ZOLL AED 3, INTL ENGLISH AHA
8502-001103-01	BLS, ZOLL AED 3, ENGLISH, AHA
8502-001103-06	BLS, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8502-001203-07	BLS, ZOLL AED 3, ENGLISH UK ERC
8502-001203-10	BLS, ZOLL AED 3, SPANISH ERC
8502-001203-23	BLS, ZOLL AED 3, SPANISH AHA
8502-001203-28	BLS, ZOLL AED 3, INTL ENGLISH AHA
8503-001103-01	BLS, W/O CARRY CASE, ZOLL AED 3, ENGLISH, AHA
8503-001103-06	BLS, W/O CARRY CASE, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8513-001103-01	BLS, W/O CARRY CASE, ZOLL AED 3, PLUSRX, ENGLISH, AHA
8501-001202-42	AUTOMATIC, ZOLL AED 3, FRENCH AHA
8502-001203-08	BLS, ZOLL AED 3, GERMAN ERC
8502-001203-09	BLS, ZOLL AED 3, GERMAN AHA
8502-001203-28	BLS, ZOLL AED 3, INTL ENGLISH AHA
8502-001203-41	BLS, ZOLL AED 3, ITALIAN AHA
8502-001203-42	BLS, ZOLL AED 3, FRENCH AHA
8501-001201-02	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH ERC
8501-001201-04	SEMI-AUTOMATIC, ZOLL AED 3, POLISH, ERC
8501-001201-08	SEMI-AUTOMATIC, ZOLL AED 3, GERMAN ERC
8501-001201-10	SEMI-AUTOMATIC, ZOLL AED 3, SPANISH ERC
8501-001201-11	SEMI-AUTOMATIC, ZOLL AED 3, ITALIAN ERC
8501-001201-17	SEMI-AUTOMATIC, ZOLL AED 3, CZECH, ERC
8501-001201-64	SEMI-AUTOMATIC, ZOLL AED 3, ROMANIAN, ERC
8502-001203-17	BLS, ZOLL AED 3, CZECH, ERC
8501-001201-16	SEMI-AUTOMATIC, ZOLL AED 3, DUTCH ERC
8501-001201-18	SEMI-AUTOMATIC, ZOLL AED 3, IBERIAN PORTUGUESE, ERC
8501-001201-61	SEMI-AUTOMATIC, ZOLL AED 3, BELGUIM, ERC
8501-001201-62	SEMI-AUTOMATIC, ZOLL AED 3, DUTCH MILITARY, ERC
8501-001201-63	SEMI-AUTOMATIC, ZOLL AED 3, LUXEMBOURG, ERC
8501-001202-02	AUTOMATIC, ZOLL AED 3, FRENCH ERC
8501-001202-08	AUTOMATIC, ZOLL AED 3, GERMAN ERC

Catalog Number	Description
8501-001202-10	AUTOMATIC, ZOLL AED 3, SPANISH ERC
8501-001202-11	AUTOMATIC, ZOLL AED 3, ITALIAN ERC
8501-001202-12	AUTOMATIC, ZOLL AED 3, INTL ENGLISH ERC
8501-001202-16	AUTOMATIC, ZOLL AED 3, DUTCH ERC
8501-001202-61	AUTOMATIC, ZOLL AED 3, BELGIUM, ERC
8501-001202-63	AUTOMATIC, ZOLL AED 3, LUXEMBOURG, ERC
8502-001203-02	BLS, ZOLL AED 3, FRENCH ERC
8502-001203-07	BLS, ZOLL AED 3, ENGLISH UK ERC
8502-001203-10	BLS, ZOLL AED 3, SPANISH ERC
8502-001203-11	BLS, ZOLL AED 3, ITALIAN ERC
8502-001203-12	BLS, ZOLL AED 3, INTL ENGLISH ERC
8502-001203-16	BLS, ZOLL AED 3, DUTCH
8502-001203-23	BLS, ZOLL AED 3, SPANISH AHA
8502-001203-61	BLS, ZOLL AED 3, BELGIUM, ERC
8502-001203-63	BLS, ZOLL AED 3, LUXEMBOURG, ERC
8501-001201-21	SEMI-AUTOMATIC, ZOLL AED 3, FINNISH
8501-001201-22	SEMI-AUTOMATIC, ZOLL AED 3, SWEDISH ERC
8501-001201-27	SEMI-AUTOMATIC, ZOLL AED 3, DANISH ERC
8501-001202-22	AUTOMATIC, ZOLL AED 3, SWEDISH ERC
8501-001202-27	AUTOMATIC, ZOLL AED 3, DANISH ERC
8502-001203-20	BLS, ZOLL AED 3, NORWEGIAN
8502-001203-21	BLS, ZOLL AED 3, FINNISH
8502-001203-22	BLS, ZOLL AED 3, SWEDISH
8502-001203-27	BLS, ZOLL AED 3, DANISH
8501-001201-07	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8501-001202-07	AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8501-001201-45	SEMI-AUTOMATIC, ZOLL AED 3, HUNGARIAN, ERC
8502-001203-45	BLS, ZOLL AED 3, HUNGARIAN, ERC
8501-001201-28	SEMI-AUTOMATIC, ZOLL AED 3, INTL ENGLISH AHA
8501-001201-41	SEMI-AUTOMATIC, ZOLL AED 3, ITALIAN AHA
8502-001203-04	BLS, ZOLL AED 3, POLISH, ERC
8502-001203-62	BLS, ZOLL AED 3, DUTCH MILITARY, ERC
8501-001201-20	SEMI-AUTOMATIC, ZOLL AED 3, NORWEGIAN
8501-001202-64	AUTOMATIC, ZOLL AED 3, ROMANIAN, ERC
8502-001203-64	BLS, ZOLL AED 3, ROMANIAN, ERC
8501-001201-56	SEMI-AUTOMATIC, ZOLL AED 3, INDONESIAN, AHA
8501-001201-71	SEMI-AUTOMATIC, ZOLL AED 3, MALAYSIAN AHA
8501-001202-33	AUTOMATIC, ZOLL AED 3, THAI AHA
8501-001201-33	SEMI-AUTOMATIC, ZOLL AED 3, THAI, AHA
8502-001203-33	BLS, ZOLL AED 3, THAI, AHA
8501-001202-56	AUTOMATIC, ZOLL AED 3, INDONESIAN, AHA
8501-001202-71	AUTOMATIC, ZOLL AED 3, MALAYSIAN AHA
8502-001203-56	BLS, ZOLL AED 3, INDONESIAN, AHA

Catalog Number	Description
8502-001203-71	BLS, ZOLL AED 3, MALAYSIAN AHA
8501-001201-19	SEMI-AUTOMATIC, ZOLL AED 3, GREEK ERC
8501-001201-51	SEMI-AUTOMATIC, ZOLL AED 3, LATVIAN ERC
8501-001201-73	SEMI-AUTOMATIC, ZOLL AED 3, SLOVAKIAN ERC
8501-001202-19	AUTOMATIC, ZOLL AED 3, GREEK ERC
8501-001202-51	AUTOMATIC, ZOLL AED 3, LATVIAN ERC
8501-001202-73	AUTOMATIC, ZOLL AED 3, SLOVAKIAN ERC
8502-001203-19	BLS, ZOLL AED 3, GREEK ERC
8502-001203-51	BLS, ZOLL AED 3, LATVIAN ERC
8502-001203-73	BLS, ZOLL AED 3, SLOVAKIAN ERC
8501-001201-35	SEMI-AUTOMATIC, ZOLL AED 3, HEBREW AHA
8501-001202-35	AUTOMATIC, ZOLL AED 3, HEBREW AHA
8502-001203-35	BLS, ZOLL AED 3, HEBREW AHA
8501-001201-34	SEMI-AUTOMATIC, ZOLL AED 3, ARABIC AHA
8501-001202-34	AUTOMATIC, ZOLL AED 3, ARABIC AHA
8502-001203-34	BLS, ZOLL AED 3, ARABIC AHA
8501-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH, AHA
8501-001102-01	AUTOMATIC, ZOLL AED 3, ENGLISH, AHA
8525-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, ARC PKG, PLUSRX, ENGLISH, AHA
8529-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, WALL CABINET, PLUSRX, ENGLISH, AHA
8529-001102-01	AUTOMATIC, ZOLL AED 3, WALL CABINET, PLUSRX, ENGLISH, AHA
8511-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, PLUSRX, ENGLISH, AHA
8511-001102-01	AUTOMATIC, ZOLL AED 3, PLUSRX, ENGLISH, AHA
8525-001102-01	AUTOMATIC, ZOLL AED 3, ARC PKG, PLUSRX, ENGLISH, AHA
8514-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 1, ENGLISH, AHA
8514-001102-01	AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 1, ENGLISH, AHA
8515-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 5, ENGLISH, AHA
8515-001102-01	AUTOMATIC, ZOLL AED 3, PLUSTRAC PROFESSIONAL 5, ENGLISH, AHA
8531-001201-41	SEMI-AUTOMATIC, ZOLL AED 3, ITALIAN AHA
8531-001201-42	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH AHA
8531-001202-41	AUTOMATIC, ZOLL AED 3, ITALIAN AHA
8531-001202-42	AUTOMATIC, ZOLL AED 3, FRENCH AHA
8532-001203-41	BLS, ZOLL AED 3, ITALIAN AHA
8532-001203-42	BLS, ZOLL AED 3, FRENCH AHA
8501-001201-44	SEMI-AUTOMATIC, ZOLL AED 3, HINDI AHA
8501-001202-44	AUTOMATIC, ZOLL AED 3, HINDI AHA
8502-001203-44	BLS, ZOLL AED 3, HINDI AHA
8501-001201-48	SEMI-AUTOMATIC, ZOLL AED 3, LITHUANIAN ERC
8501-001202-48	AUTOMATIC, ZOLL AED 3, LITHUANIAN ERC
8502-001203-48	BLS, ZOLL AED 3, LITHUANIAN ERC
8501-001201-52	SEMI-AUTOMATIC, ZOLL AED 3, CROATIAN ERC
8501-001202-52	AUTOMATIC, ZOLL AED 3, CROATIAN ERC
8502-001203-52	BLS, ZOLL AED 3, CROATIAN ERC

Catalog Number	Description
8501-001201-53	SEMI-AUTOMATIC, ZOLL AED 3, SLOVENIAN ERC
8501-001202-53	AUTOMATIC, ZOLL AED 3, SLOVENIAN ERC
8502-001203-53	BLS, ZOLL AED 3, SLOVENIAN ERC
8501-001201-55	SEMI-AUTOMATIC, ZOLL AED 3, TURKISH ERC
8501-001202-55	AUTOMATIC, ZOLL AED 3, TURKISH ERC
8502-001203-55	BLS, ZOLL AED 3, TURKISH ERC
8501-001201-70	SEMI-AUTOMATIC, ZOLL AED 3, VIETNAMESE AHA
8501-001202-70	AUTOMATIC, ZOLL AED 3, VIETNAMESE AHA
8502-001203-70	BLS, ZOLL AED 3, VIETNAMESE AHA
8501-001201-72	SEMI-AUTOMATIC, ZOLL AED 3, BULGARIAN ERC
8501-001202-72	AUTOMATIC, ZOLL AED 3, BULGARIAN ERC
8502-001203-72	BLS, ZOLL AED 3, BULGARIAN ERC
8501-001201-74	SEMI-AUTOMATIC, ZOLL AED 3, TAGALOG AHA
8501-001202-74	AUTOMATIC, ZOLL AED 3, TAGALOG AHA
8502-001203-74	BLS, ZOLL AED 3, TAGALOG AHA
8501-001201-81	SEMI-AUTOMATIC, ZOLL AED 3, THAI JAPAN AHA
8501-001202-81	AUTOMATIC, ZOLL AED 3, THAI JAPAN AHA
8502-001203-81	BLS, ZOLL AED 3, THAI JAPAN AHA
8526-001101-01	SEMI-AUTOMATIC, ZOLL AED 3, LAW ENFORCEMENT PKG, ENGLISH, AHA
8526-001102-01	AUTOMATIC, ZOLL AED 3, LAW ENFORCEMENT PKG, ENGLISH, AHA
8532-001203-36	BLS, ZOLL AED 3, JAPANESE, JRC
8533-001203-36	BLS, ZOLL AED 3, W/O CARRY CASE, JAPANESE, JRC
8531-001201-36	SEMI-AUTOMATIC, ZOLL AED 3, JAPANESE, JRC
8562-001206-22	BLS, AVIATION, ZOLL AED 3, SWEDISH ERC

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>	REF
Defibrillation Accessories	
CPR UNI-PADZ	8900-000260
CPR UNI-PADZ	8900-000270
CPR UNI-PADZ	8900-000280
CPR UNI-PADZ, (U.S. only)	8900-000280-01
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01
CPR STAT-PADZ ELECTRODE, SINGLE	8900-0402
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01
ONESTEP BASIC ELECTRODES WITH GREEN CONNECTOR	8900-000250-05
ONESTEP CPR A/A ELECTRODES WITH GREEN CONNECTOR	8900-000251-05
ONESTEP PEDIATRIC ELECTRODES WITH GREEN CONNECTOR	8900-000252-05
Battery Accessories	
ZOLL AED 3 BATTERY PACK	8000-000696
ZOLL AED 3 AVIATION BATTERY PACK	8000-000697
ZOLL AED 3 BATTERY PACK, JAPANESE	8000-000696-36
ZOLL AED 3 AVIATION BATTERY PACK, SWEDISH	8000-000697-22
Simulation/Training Accessories	
CPR UNI-PADZ TRAINING KIT	8900-000264
CPR UNI-PADZ, II TRAINING KIT	8900-000274
CPR UNI-PADZ, III TRAINING KIT	8900-000284
Non-Medical Device Accessories	
AED PLUS 2 CARRY CASE	8000-001250
POUCH, BATTERY, ZOLL AED 3	8000-001251
SHOULDER STRAP, CARRY CASE, ZOLL AED 3	8000-001252
SMALL RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001253
LARGE RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001254
BRACKET, WALL MOUNT, ZOLL AED 3	8000-001255
WALL CABINET, STANDARD SURFACE, ZOLL AED 3	8000-001256
WALL CABINET, SEMI-RECESSED, ZOLL AED 3	8000-001257
WALL CABINET, FULLY-RECESSED, ZOLL AED 3	8000-001258
STROBE LIGHT, AED PLUS SERIES	8000-001259
ILCOR FLUSH WALL SIGN (AED)	8000-001260
ILCOR 3-D WALL SIGN (AED)	8000-001261
ILCOR FLUSH WALL SIGN (DAE)	8000-001262

ILCOR 3-D WALL SIGN (DAE)	8000-001263
ILCOR FLUSH WALL SIGN (DEA)	8000-001264
ILCOR 3-D WALL SIGN (DEA)	8000-001265
BRACKET, WALL MOUNT, CASE, ZOLL AED 3	8000-001266
STROBE LIGHT W/PLATE, AED PLUS SERIES	8000-001267
ZOLL AED SIMULATOR	8000-000925
SOFT CARRY CASE, ZOLL AED 3	8000-001280

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 procedures 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.

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

Type examination certificate: **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
EN 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
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
EN 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-9: 2013	Medical Electrical Equipment - Part 1-9: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Environmentally Conscious Design
EN 60601-1-11: 2010	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 1041: 2008	Information supplied by the manufacturer of medical devices
EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
IEC 62366: 2014	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-4: 2010	Medical electrical equipment - Part 2-4: Particular requirements for the Safety of Cardiac Defibrillators

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Conformity Standard	Description of Standard
EN 62304: 2006	Medical device software – Software life-cycle processes
EN 1789: 2014	Medical vehicles and their equipment – Road ambulances
IEC 60086-4	Primary Batteries - Part 4: Safety of Lithium Batteries ¹
RTCA/DO-227A amended by TSO C142b	Minimum Operational Performance Standards for Non-Rechargeable Lithium Batteries as amended by Appendix 1 of TSO-C142b ¹
MEDDEV 2.7.1: 2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
EN ISO 14155: 2011	Clinical investigation of medical devices for human subjects – Good clinical practice
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

¹ Applies to the AED 3 Aviation Battery Pack only

SCHEDULE 2

Catalog Number	Description	Class	GMDN Code
1128-001201-13	MAIN ASSEMBLY, SEMI-AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	47910
1128-001202-13	MAIN ASSEMBLY, AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	48047
1128-001203-13	MAIN ASSEMBLY, BLS, ZOLL AED 3, AUSTRALIA	IIb	48049
1128-001204-13	MAIN ASSEMBLY, AVIATION SEMI-AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	47910
1128-001205-13	MAIN ASSEMBLY, AVIATION AUTOMATIC, ZOLL AED 3, AUSTRALIA	IIb	48047
1128-001206-13	MAIN ASSEMBLY, AVIATION BLS, ZOLL AED 3, AUSTRALIA	IIb	48049

Accessory Description	Accessory Catalog Number	GMDN Code
Defibrillation Accessories		
CPR UNI-PADZ	8900-000260	45806, 42404
CPR UNI-PADZ	8900-000270	45806, 42404
CPR UNI-PADZ	8900-000280	45806, 42404
CPR UNI-PADZ, (U.S. only)	8900-000280-01	45806, 42404
CPR-D-PADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP	8900-0800-01	45806
CPR STAT-PADZ ELECTRODE, SINGLE	8900-0402	45806
STAT-PADZ II ELECTRODE, SINGLE	8900-0801-01	45806
PEDI-PADZ II ELECTRODES - ONE PAIR	8900-0810-01	42404
ONESTEP BASIC ELECTRODES WITH GREEN CONNECTOR	8900-000250-05	45806
ONESTEP CPR A/A ELECTRODES WITH GREEN CONNECTOR	8900-000251-05	45806
ONESTEP PEDIATRIC ELECTRODES WITH GREEN CONNECTOR	8900-000252-05	42404
Battery Accessories		
ZOLL AED 3 BATTERY PACK	8000-000696	48058
ZOLL AED 3 AVIATION BATTERY PACK	8000-000697	48058
Non-medical device accessories		
CPR UNI-PADZ TRAINING KIT	8900-000264	
CPR UNI-PADZ, II TRAINING KIT	8900-000274	
CPR UNI-PADZ, III TRAINING KIT	8900-000284	
AED PLUS 2 CARRY CASE	8000-001250	
POUCH, BATTERY, ZOLL AED 3	8000-001251	
SHOULDER STRAP, CARRY CASE, ZOLL AED 3	8000-001252	

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

SMALL RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001253
LARGE RIGID PLASTIC CARRY CASE, ZOLL AED 3	8000-001254
BRACKET, WALL MOUNT, ZOLL AED 3	8000-001255
WALL CABINET, STANDARD SURFACE, ZOLL AED 3	8000-001256
WALL CABINET, SEMI-RECESSED, ZOLL AED 3	8000-001257
WALL CABINET, FULLY-RECESSED, ZOLL AED 3	8000-001258
STROBE LIGHT, AED PLUS SERIES	8000-001259
ILCOR FLUSH WALL SIGN (AED)	8000-001260
ILCOR 3-D WALL SIGN (AED)	8000-001261
ILCOR FLUSH WALL SIGN (DAE)	8000-001262
ILCOR 3-D WALL SIGN (DAE)	8000-001263
ILCOR FLUSH WALL SIGN (DEA)	8000-001264
ILCOR 3-D WALL SIGN (DEA)	8000-001265
BRACKET, WALL MOUNT, CASE, ZOLL AED 3	8000-001266
STROBE LIGHT W/PLATE, AED PLUS SERIES	8000-001267
ZOLL AED SIMULATOR	8000-000925
SOFT CARRY CASE, ZOLL AED 3	8000-001280

Authorised signatory:

Signature

Name: Elizabeth McMeniman
Position: Director, Regulatory Affairs
Location: Chelmsford, MA USA

December 8, 2020
Date