

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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

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

Date

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 1 of 11	Document Number: 9652-000138		Revision: YC

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
8502-001203-07	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
8513-001103-01	BLS, W/O CARRY CASE, ZOLL AED 3, PLUSRX, ENGLISH, AHA
8501-001202-42	AUTOMATIC, ZOLL AED 3, FRENCH AHA
8501-001201-42	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH AHA
8502-001203-08	BLS, ZOLL AED 3, GERMAN ERC
8502-001203-09	BLS, ZOLL AED 3, GERMAN AHA
8501-001201-09	SEMI-AUTOMATIC, ZOLL AED 3, GERMAN AHA
8501-001202-09	AUTOMATIC, ZOLL AED 3, GERMAN 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
8501-001202-04	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
8501-001202-17	AUTOMATIC, ZOLL AED 3, CZECH, 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

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 2 of 11	Document Number: 9652-000138	Revision: YC	

Catalog Number	Description
8501-001201-18	SEMI-AUTOMATIC, ZOLL AED 3, IBERIAN PORTUGUESE, ERC
8501-001202-18	AUTOMATIC, ZOLL AED 3, IBERIAN PORTUGUESE, ERC
8502-001203-18	BLS, 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
8501-001202-62	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
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
8502-001203-11	BLS, ZOLL AED 3, ITALIAN ERC
8502-001203-12	BLS, ZOLL AED 3, INTL ENGLISH ERC
8502-001203-16	BLS, ZOLL AED 3, DUTCH
8502-001203-61	BLS, ZOLL AED 3, BELGIUM, ERC
8502-001203-63	BLS, ZOLL AED 3, LUXEMBOURG, ERC
8501-001202-21	AUTOMATIC, ZOLL AED 3, FINNISH
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
8501-001202-07	AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8501-001201-45	SEMI-AUTOMATIC, ZOLL AED 3, HUNGARIAN, ERC
8501-001202-45	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
8501-001202-41	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

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 3 of 11	Document Number: 9652-000138		Revision: YC

Catalog Number	Description
8501-001201-20	SEMI-AUTOMATIC, ZOLL AED 3, NORWEGIAN
8501-001202-20	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
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

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105
Page: 4 of 11	Document Number: 9652-000138	Revision: YC

Catalog Number	Description
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
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
8522-001103-01	BLS, ZOLL AED 3, ENGLISH AHA, PACKAGE 1

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105
Page: 5 of 11	Document Number: 9652-000138	Revision: YC

Catalog Number	Description
8523-001103-01	BLS, ZOLL AED 3, ENGLISH AHA, PACKAGE 2
8501-001201-49	SEMI-AUTOMATIC, ZOLL AED 3, SERBIAN
8501-001202-49	AUTOMATIC, ZOLL AED 3, SERBIAN ERC
8502-001203-49	BLS, ZOLL AED 3, SERBIAN ERC
8501-001202-58	AUTOMATIC, ZOLL AED 3, NEW ZEALAND
8502-001203-58	BLS, ZOLL AED 3, NEW ZEALAND
8501-001201-58	SEMI-AUTOMATIC, ZOLL AED 3, NEW ZEALAND
8529-001102-26	AUTOMATIC, ZOLL AED 3, WALL CABINET, FRENCH CANADIAN, AHA
8529-001102-06	AUTOMATIC, ZOLL AED 3, WALL CABINET, ENGLISH, CANADIAN, AHA
8504-001103-06	BLS, W/O CARRY CASE, CPR STAT PADZ, ZOLL AED 3, FRENCH CANADIAN, AHA
8504-001103-26	BLS, W/O CARRY CASE, CPR STAT PADZ, ZOLL AED 3, ENGLISH, CANADIAN, AHA
8501-001201-43	SEMI-AUTOMATIC, ZOLL AED 3, FARSI, AHA
8501-001202-43	AUTOMATIC, ZOLL AED 3, FARSI, AHA
8502-001203-43	BLS, ZOLL AED 3, FARSI, AHA
8501-001201-14	SEMI-AUTOMATIC, ZOLL AED 3, KOREAN AHA
8502-001203-14	BLS, ZOLL AED 3, KOREAN AHA
8501-001201-59	SEMI-AUTOMATIC, ZOLL AED 3, SINGAPORE
8501-001202-59	AUTOMATIC, ZOLL AED 3, SINGAPORE
8502-001203-59	BLS, ZOLL AED 3, SINGAPORE
8560-001205-07	AUTOMATIC, AVIATION, ZOLL AED 3, ENGLISH UK ERC
8501-001201-25	SEMI-AUTOMATIC, ZOLL AED 3, TRADITIONAL CHINESE, AHA
8501-001202-25	AUTOMATIC, ZOLL AED 3, TRADITIONAL CHINESE, AHA
8502-001203-25	BLS, ZOLL AED 3, TRADITIONAL CHINESE, AHA
8501-001201-24	SEMI-AUTOMATIC, ZOLL AED 3, BRAZILIAN PORTUGUESE AHA
8501-001202-24	AUTOMATIC, ZOLL AED 3, BRAZILIAN PORTUGUESE AHA
8502-001203-24	BLS, ZOLL AED 3, BRAZILIAN PORTUGUESE AHA
8560-001104-06	SEMI-AUTOMATIC, ZOLL AED 3, AVIATION, ENGLISH, CANADIAN, AHA
8560-001104-26	SEMI-AUTOMATIC, ZOLL AED 3, AVIATION, FRENCH CANADIAN, AHA
8560-001105-06	AUTOMATIC, ZOLL AED 3, AVIATION, ENGLISH, CANADIAN, AHA
8560-001105-26	AUTOMATIC, ZOLL AED 3, AVIATION, FRENCH CANADIAN, AHA
8562-001106-06	BLS, ZOLL AED 3, AVIATION, ENGLISH, CANADIAN, AHA
8562-001106-26	BLS, ZOLL AED 3, AVIATION, FRENCH CANADIAN, AHA
8529-001101-26	SEMI-AUTOMATIC, ZOLL AED 3, WALL CABINET, FRENCH CANADIAN, AHA
8529-001101-06	SEMI-AUTOMATIC, ZOLL AED 3, WALL CABINET, ENGLISH, CANADIAN, AHA
8560-001105-01	AUTOMATIC, AVIATION, ZOLL AED 3, ENGLISH, AHA
8560-001104-01	SEMI-AUTOMATIC, ZOLL AED 3, AVIATION, ENGLISH, AHA
8562-001106-01	BLS, ZOLL AED 3, AVIATION, ENGLISH, ENGLISH, AHA
8560-001205-08	AUTOMATIC, AVIATION ZOLL AED 3, GERMAN ERC
8560-001204-08	SEMI AUTOMATIC, AVIATION ZOLL AED 3, GERMAN ERC
8562-001206-08	BLS, ZOLL AED 3, AVIATION, GERMAN ERC

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 6 of 11	Document Number: 9652-000138	Revision: YC	

Catalog Number	Description
8560-001205-09	AUTOMATIC, AVIATION, ZOLL AED 3, GERMAN AHA
8562-001206-09	BLS, ZOLL AED 3, AVIATION, ERC, GERMAN
8560-001205-12	AUTOMATIC, AVIATION, ZOLL AED 3, INTL ENGLISH ERC
8560-001204-12	SEMI AUTOMATIC, AVIATION, ZOLL AED 3, INTL ENGLISH ERC
8560-001205-27	AUTOMATIC, AVIATION, ZOLL AED 3, DANISH ERC
8560-001204-27	SEMI AUTOMATIC, AVIATION, ZOLL AED 3, DANISH ERC
8562-001206-27	BLS, ZOLL AED 3, AVIATION, DANISH ERC
8502-001203-54	BLS, ZOLL AED 3, TAIWAN, AHA
8562-001206-12	BLS, ZOLL AED 3, AVIATION, ENGLISH INTL
8560-001204-02	SEMI AUTOMATIC, AVIATION, ZOLL AED 3, FRENCH ERC
8560-001205-02	AUTOMATIC, AVIATION, ZOLL AED 3, FRENCH ERC
8562-001206-02	BLS, ZOLL AED 3, AVIATION, ERC, FRENCH
8531-001201-02	SEMI-AUTOMATIC, ZOLL AED 3, FRENCH ERC
8531-001201-04	SEMI-AUTOMATIC, ZOLL AED 3, POLISH ERC
8531-001201-07	SEMI-AUTOMATIC, ZOLL AED 3, ENGLISH UK ERC
8531-001201-08	SEMI-AUTOMATIC, ZOLL AED 3, GERMAN ERC
8531-001201-10	SEMI-AUTOMATIC, ZOLL AED 3, SPANISH ERC
8531-001201-11	SEMI-AUTOMATIC, ZOLL AED 3, ITALIAN ERC
8531-001201-12	SEMI-AUTOMATIC, ZOLL AED 3, INTL ENGLISH ERC
8531-001201-16	SEMI-AUTOMATIC, ZOLL AED 3, DUTCH ERC
8531-001201-18	SEMI-AUTOMATIC, ZOLL AED 3, IBERIAN PORTUGESE ERC
8531-001201-25	SEMI-AUTOMATIC, ZOLL AED 3, TRADITIONAL CHINESE AHA
8531-001201-33	SEMI-AUTOMATIC, ZOLL AED 3, THAI AHA
8531-001201-56	SEMI-AUTOMATIC, ZOLL AED 3, INDONESIAN AHA
8531-001201-59	SEMI-AUTOMATIC, ZOLL AED 3, SINGAPORE AHA
8531-001201-61	SEMI-AUTOMATIC, ZOLL AED 3, BELGIUM ERC
8531-001201-70	SEMI-AUTOMATIC, ZOLL AED 3, VIETNAMESE AHA
8531-001201-71	SEMI-AUTOMATIC, ZOLL AED 3, MALAYSIAN AHA
8531-001202-02	AUTOMATIC, ZOLL AED 3, FRENCH, ERC
8531-001202-04	AUTOMATIC, ZOLL AED 3, POLISH, ERC
8531-001202-07	AUTOMATIC, ZOLL AED 3, UK ENGLISH, ERC
8531-001202-08	AUTOMATIC, ZOLL AED 3, GERMAN, ERC
8531-001202-10	AUTOMATIC, ZOLL AED 3, SPANISH, ERC
8531-001202-11	AUTOMATIC, ZOLL AED 3, ITALIAN, ERC
8531-001202-12	AUTOMATIC, ZOLL AED 3, INTL ENGLISH, ERC
8531-001202-16	AUTOMATIC, ZOLL AED 3, DUTCH, ERC
8531-001202-18	AUTOMATIC, ZOLL AED 3, IBERIAN PORTUGESE, ERC
8531-001202-25	AUTOMATIC, ZOLL AED 3, TRADITIONAL CHINESE, AHA
8531-001202-33	AUTOMATIC, ZOLL AED 3, THAI, AHA
8531-001202-56	AUTOMATIC, ZOLL AED 3, INDONESIAN, AHA

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 7 of 11	Document Number: 9652-000138		Revision: YC

Catalog Number	Description
8531-001202-59	AUTOMATIC, ZOLL AED 3, SINGAPORE, AHA
8531-001202-61	AUTOMATIC, ZOLL AED 3, BELGIUM, ERC
8531-001202-70	AUTOMATIC, ZOLL AED 3, VIETNAMESE, AHA
8531-001202-71	AUTOMATIC, ZOLL AED 3, MALAYSIAN, AHA
8532-001203-02	BLS, ZOLL AED 3, FRENCH, ERC
8533-001203-02	BLS, ZOLL AED 3, FRENCH, ERC
8532-001203-04	BLS, ZOLL AED 3, POLISH, ERC
8533-001203-04	BLS, ZOLL AED 3, POLISH, ERC
8532-001203-07	BLS, ZOLL AED 3, UK ENGLISH, ERC
8533-001203-07	BLS, ZOLL AED 3, UK ENGLISH, ERC
8532-001203-08	BLS, ZOLL AED 3, GERMAN, ERC
8533-001203-08	BLS, ZOLL AED 3, GERMAN, ERC
8532-001203-10	BLS, ZOLL AED 3, SPANISH, ERC
8533-001203-10	BLS, ZOLL AED 3, SPANISH, ERC
8532-001203-11	BLS, ZOLL AED 3, ITALIAN, ERC
8533-001203-11	BLS, ZOLL AED 3, ITALIAN, ERC
8532-001203-12	BLS, ZOLL AED 3, INTL ENGLISH, ERC
8532-001203-16	BLS, ZOLL AED 3, DUTCH, ERC
8533-001203-16	BLS, ZOLL AED 3, DUTCH, ERC
8532-001203-18	BLS, ZOLL AED 3, IBERIAN PORTUGUESE, ERC
8533-001203-18	BLS, ZOLL AED 3, IBERIAN PORTUGUESE, ERC
8532-001203-25	BLS, ZOLL AED 3, TRADITIONAL CHINESE AHA
8532-001203-33	BLS, ZOLL AED 3, THAI, AHA
8532-001203-54	BLS, ZOLL AED 3, TAIWANESE, AHA
8532-001203-56	BLS, ZOLL AED 3, INDONESIAN, AHA
8532-001203-59	BLS, ZOLL AED 3, SINGAPORE, AHA
8532-001203-61	BLS, ZOLL AED 3, BELGIUM, ERC
8533-001203-61	BLS, ZOLL AED 3, BELGIUM, ERC
8532-001203-70	BLS, ZOLL AED 3, VIETNAMESE, AHA
8532-001203-71	BLS, ZOLL AED 3, MALAYSIAN, AHA

Class IIb Battery Accessories

Catalog Number	Description
8000-000696	ZOLL AED 3 BATTERY PACK
8000-000697	ZOLL AED 3 AVIATION BATTERY PACK
8000-000696-36	ZOLL AED 3 BATTERY PACK, JAPANESE
8000-000697-22	ZOLL AED 3 AVIATION BATTERY PACK, SWEDISH
8000-000697-06	ZOLL AED 3 AVIATION BATTERY PACK, CANADIAN ENGLISH
8000-000697-02	ZOLL AED 3 AVIATION BATTERY PACK, FRENCH
8000-000697-08	ZOLL AED 3 AVIATION BATTERY PACK, GERMAN
8000-000697-27	ZOLL AED 3 AVIATION BATTERY PACK, DANISH

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 8 of 11	Document Number: 9652-000138	Revision: YC	

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

Classification: IIb

GMDN code and term: 47910 Non-rechargeable semi-automatic external defibrillator
48047 Non-rechargeable public automated external defibrillator
48049 Non-rechargeable professional semi-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 certificates: No. QS6 079546 0021 (MDSAP, RA-CERT-000118)
No. Q5 079546 0029 (QMS/ISO Certificate, RA-CERT-000124)
No. G1 079546 0028 (EC, RA-CERT-000157)

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

Standards applied: See Schedule 1

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 9 of 11	Document Number: 9652-000138		Revision: YC

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

SCHEDULE 1

Conformity Standard	Description of Standard
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971: 2019	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
IEC 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 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
IEC 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 20417: 2021	Medical devices — Information to be supplied by the manufacturer
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
IEC 62304: 2015	Medical device software – Software life-cycle processes
EN 1789: 2014	Medical vehicles and their equipment – Road ambulances
IEC 60086-4: 2014	Primary Batteries - Part 4: Safety of Lithium Batteries ¹
RTCA/DO-227A: 2018 as 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

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 10 of 11	Document Number: 9652-000138		Revision: YC

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

AED 3 CATALOG LIST AND ACCESSORIES

Catalog Number	Description
Defibrillation Device	
1128-001201-13	MAIN ASSEMBLY, SEMI-AUTOMATIC, ZOLL AED 3, AUSTRALIA
1128-001202-13	MAIN ASSEMBLY, AUTOMATIC, ZOLL AED 3, AUSTRALIA
1128-001203-13	MAIN ASSEMBLY, BLS, ZOLL AED 3, AUSTRALIA
1128-001204-13	MAIN ASSEMBLY, AVIATION SEMI-AUTOMATIC, ZOLL AED 3, AUSTRALIA
1128-001205-13	MAIN ASSEMBLY, AVIATION AUTOMATIC, ZOLL AED 3, AUSTRALIA
1128-001206-13	MAIN ASSEMBLY, AVIATION BLS, ZOLL AED 3, AUSTRALIA
Battery Accessories	
8000-000696	ZOLL AED 3 BATTERY PACK
8000-000697	ZOLL AED 3 AVIATION BATTERY PACK

Authorized signatory:

Natalie England, Manager, Regulatory Affairs

Date

Document Title: DECLARATION OF CONFORMITY, MDD, ZOLL AED 3		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page: 11 of 11	Document Number: 9652-000138		Revision: YC