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: Powerheart® G3 Adult Electrode (9131-001 and 9131-031)
Powerheart® G3 Adult Electrode, Polarized (9660-001)
Powerheart® G3 Pediatric Electrode (9730-002)
Powerheart® G5 Adult Electrode (XELAED001B, XELAED001C)
Powerheart® G5 Adult Electrode with ICPR (XELAED002B, XELAED002C)
Powerheart® G5 Pediatric Electrode (XELAED003A, XELAED003C)

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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: 2021.12.23 16:19:24 Z

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

Date

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):	Powerheart® G3 Adult Electrode (9131-001 and 9131-031) Powerheart® G3 Adult Electrode, Polarized (9660-001) Powerheart® G3 Pediatric Electrode (9730-002) Powerheart® G5 Adult Electrode (XELAED001B, XELAED001C) Powerheart® G5 Adult Electrode with CPR Device (XELAED002B, XELAED002C) Powerheart® G5 Pediatric Electrode (XELAED003A, XELAED003C)
Classification:	Class IIb
GMDN code and term:	44771, External defibrillator electrode, adult, single-use (XELAED001B, XELAED001C, XELAED002B, XELAED002C, 9131-001, 9131-031, 9660-001) 41587, External defibrillator electrode, paediatric, single-use (XELAED003A, XELAED003C, 9730-002)
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:	**Q5 079546 0029, ISO 13485 (RA-CERT-000124)** **QS6 079546 0021, MDSAP (RA-CERT-000118)** **G1 079546 0028, EC (RA-CERT-000157)**
Design examination certificate: (if applicable)	N/A
Standards applied:	See Schedule 1

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AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Schedule 1

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
IEC 60601-1: 2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-6: 2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366: 2015	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-4: 2018	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 10993-1: 2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2014	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
EN ISO 15223-1: 2021	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)
EN 20417: 2021	Medical devices — Information to be supplied by the manufacturer

Authorized signatory:

Natalie England Digitally signed by Natalie England
Date: 2021.12.23 16:19:57 Z

Natalie England, Manager, Regulatory Affairs

Name, Position

Date