DECLARATION OF CONFORMITY

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
USA

EC REP **ZOLL International Holding B.V.**
Newtonweg 18
6662 PV ELST
The Netherlands

CH REP **ZOLL Medical Switzerland A.G.**
Bahnhofstrasse 20
6300, Zug
Switzerland

Product: Powerheart® G3 non rechargeable batteries
Powerheart® G5 non rechargeable batteries
See 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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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: 2021.12.23 16:17:52 Z

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

Date

Catalog Number	Description	Compatible Device
9145-301	Battery, AED G3, Powerheart Pro, Yellow, Repl Smart PCBA	Powerheart® G3 Elite
9146-301	Battery, G3 AED, Powerheart, White, Repl Smart PCBA	Powerheart® G3 Elite
9146-302	Battery, G3 AED, Powerheart, Yellow, Repl Smart PCBA	Powerheart® G3 Elite
9146-309	Battery, G3 AED, Powerheart, JP-O, Yellow, Repl Smart PCBA	Powerheart® G3 Elite
9146-702	Battery, G3 Elite AED, Powerheart, Orange	Powerheart® G3 Elite
9147-201-TSO	AED Battery, 9300E/A, 9390E/A, EXT LIFE, TSO, REPL SMART PCBA	Powerheart® G3 Elite
XBTAED001A	Battery, Powerheart G5	Powerheart® G5
XBTAED005A-TSO	Battery, G5 LiSO2, TSO-C142a, w/insert	Powerheart® G5
XBTAED005A	Battery, Powerheart G5, LiSO2, TSO-C142a	Powerheart® G5

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 non rechargeable batteries Powerheart® G5 non rechargeable batteries Schedule 1
Classification:	Class I
GMDN code and term:	38558 Primary Battery
Scope of application:	All products to which the full quality assurance procedure 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.

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:

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
IEC 60601-2-4: 2018	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
IEC 60086-4: 2014	Primary batteries – part 4: safety of lithium batteries
MEDDEV 2.7.1: 2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
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

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Schedule 1

Catalog Number	Description	Compatible Device
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XBTAED005A	Battery, Powerheart G5, LiSO2, TSO-C142a	Powerheart® G5

Authorized signatory:

Natalie England Digitally signed by Natalie England
Date: 2021.12.23 16:18:21 Z

Natalie England, Manager, Regulatory Affairs
Name, Position

Date