DECLARATION OF CONFORMITY

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

ZOLL International Holding B.V.
*Einsteinweg 8A
6662 PW ELST
The Netherlands

ZOLL Medical Switzerland AG
*Baarerstrasse 8
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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on waste electrical and electronic equipment (WEEE).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.

Daniel Connell

Digitally signed by Daniel Connell
Date: 2023.06.16 16:39:44 -04'00'

June 16, 2023

Name: Daniel Connell
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	Powerhear[t]® G5

***EU Representative Address Change**

Please note a change to ZOLL's EU Representative address:

Previous Address:

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

New Address:

ZOLL International Holding B.V.
Einsteinweg 8A
6662 **PW** ELST
The Netherlands

As we implement this address change it will be reflected on all applicable product labelling.

***Swiss Representative Address Change**

Please note a change to ZOLL's Swiss Representative address:

Previous Address:

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

New Address:

ZOLL Medical Switzerland AG
Baarerstrasse 8
6300, Zug
Switzerland

As we implement this address change it will be reflected on applicable product labelling.