

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® G5, Automatic (G5A)
Powerheart® G5, Semi-Automatic (G5S)
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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European parliament and of the council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE).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.


June 16, 2023

Name: Daniel Connell
Position: Manager, Regulatory Affairs
Location: Chelmsford, MA


Date

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Catalog Number	Description
G5A-00A	Powerheart® G5 Kit, Auto, International Eng
G5A-00C	Powerheart® G5 Kit, Auto, International Eng, CPRD
G5A-00A-TSO	Powerheart® G5 Kit, Auto, Int'l English, TSO
G5A-00C-TSO	Powerheart® G5 Kit, Auto, Int'l English, CPRD, TSO
G5S-00A	Powerheart® G5 Kit, Semi, International Eng
G5S-00C	Powerheart® G5 Kit, Semi, International Eng, CPRD
G5S-00A-TSO	Powerheart® G5 Kit, Semi, Int'l English, TSO
G5S-00C-TSO	Powerheart® G5 Kit, Semi, Int'l English, CPRD, TSO
G5A-01A	Powerheart® G5 Kit, Auto, US English
G5A-01C	Powerheart® G5 Kit, Auto, US English, CPRD
G5S-01A	Powerheart® G5 Kit, Semi, US English
G5S-01C	Powerheart® G5 Kit, Semi, US English, CPRD
G5A-02A	Powerheart® G5 Kit, Auto, UK English
G5A-02C	Powerheart® G5 Kit, Auto, UK English, CPRD
G5A-02A-TSO	Powerheart® G5 Kit, Auto, UK, TSO
G5A-02C-TSO	Powerheart® G5 Kit, Auto, UK, CPRD, TSO
G5S-02A	Powerheart® G5 Kit, Semi, UK English
G5S-02C	Powerheart® G5 Kit, Semi, UK English, CPRD
G5A-03A	Powerheart® G5 Kit, Auto, LA Sp-Intl Eng
G5A-03C	Powerheart® G5 Kit, Auto, LA Sp-Intl Eng, CPRD
G5S-03A	Powerheart® G5 Kit, Semi, LA Sp-Intl Eng
G5S-03C	Powerheart® G5 Kit, Semi, LA Sp-Intl Eng, CPRD
G5A-04A	Powerheart® G5 Kit, Auto, IB Port-Int'l English
G5A-04C	Powerheart® G5 Kit, Auto, IB Port-Int'l English, CPRD
G5S-04A	Powerheart® G5 Kit, Semi, IB Port-Int'l English
G5S-04C	Powerheart® G5 Kit, Semi, IB Port-Int'l English, CPRD
G5A-05A	Powerheart® G5 Kit, Auto, ESP (IB)-Int'l English
G5A-05C	Powerheart® G5 Kit, Auto, ESP (IB)-Int'l English, CPRD
G5S-05A	Powerheart® G5 Kit, Semi, ESP (IB)-Int'l English
G5S-05C	Powerheart® G5 Kit, Semi, ESP (IB)-Int'l English, CPRD
G5A-06A	Powerheart® G5 Kit, Auto, Int'l English-Arabic
G5A-06C	Powerheart® G5 Kit, Auto, Int'l English-Arabic, CPRD
G5S-06A	Powerheart® G5 Kit, Semi, Int'l English-Arabic
G5S-06C	Powerheart® G5 Kit, Semi, Int'l English-Arabic, CPRD
G5A-07A	Powerheart® G5 Kit, Auto, Simp Chi, Mand-Intl Eng
G5A-07C	Powerheart® G5 Kit, Auto, Simp Chi, Mand-Intl Eng, ICPR
G5S-07A	Powerheart® G5 Kit, Semi, Simp Chi, Mand-Intl Eng
G5S-07C	Powerheart® G5 Kit, Semi, Simp Chi, Mand-Intl Eng, ICPR
G5A-08A	Powerheart® G5 Kit, Auto, Ger-Int'l English
G5A-08C	Powerheart® G5 Kit, Auto, Ger-Int'l English, CPRD
G5S-08A	Powerheart® G5 Kit, Semi, Ger-Int'l English

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Catalog Number	Description
G5S-08C	Powerheart® G5 Kit, Semi, Ger-Int'l English, CPRD
G5A-10A	Powerheart® G5 Kit, Auto, ITA/Intl Eng
G5A-10C	Powerheart® G5 Kit, Auto, ITA/Intl Eng, CPRD
G5S-10A	Powerheart® G5 Kit, Semi, Italian-Int'l English
G5S-10C	Powerheart® G5 Kit, Semi, Italian-Int'l English, CPRD
G5A-11A	Powerheart® G5 Kit, Auto, French-Int'l English
G5A-11C	Powerheart® G5 Kit, Auto, French-Int'l English, CPRD
G5S-11A	Powerheart® G5 Kit, Semi, French-Int'l English
G5S-11C	Powerheart® G5 Kit, Semi, French-Int'l English, CPRD
G5A-12A	Powerheart® G5 Kit, Auto, Czech-Int'l English
G5A-12C	Powerheart® G5 Kit, Auto, Czech-Int'l English, CPRD
G5S-12A	Powerheart® G5 Kit, Semi, Czech-Int'l English
G5S-12C	Powerheart® G5 Kit, Semi, Czech-Int'l English, CPRD
G5A-13A	Powerheart® G5 Kit, Auto, Swedish-Int'l English
G5A-13C	Powerheart® G5 Kit, Auto, Swedish-Int'l English, CPRD
G5S-13A	Powerheart® G5 Kit, Semi, Swedish-Int'l English
G5S-13C	Powerheart® G5 Kit, Semi, Swedish-Int'l English, CPRD
G5A-14A	Powerheart® G5 Kit, Auto, Danish-Int'l English
G5A-14C	Powerheart® G5 Kit, Auto, Danish-Int'l English, CPRD
G5S-14A	Powerheart® G5 Kit, Semi, Danish-Int'l English
G5S-14C	Powerheart® G5 Kit, Semi, Danish-Int'l English, CPRD
G5A-15A	Powerheart® G5 Kit, Auto, Dutch-Int'l English
G5A-15C	Powerheart® G5 Kit, Auto, Dutch-Int'l English, CPRD
G5S-15A	Powerheart® G5 Kit, Semi, Dutch-Int'l English
G5S-15C	Powerheart® G5 Kit, Semi, Dutch-Int'l English, CPRD
G5A-16A	Powerheart® G5 Kit, Auto, FIN-Intl ENG
G5A-16C	Powerheart® G5 Kit, Auto, FIN-Intl ENG, CPRD
G5S-16A	Powerheart® G5 Kit, Semi, FIN-Intl ENG
G5S-16C	Powerheart® G5 Kit, Semi, FIN-Intl ENG, CPRD
G5A-17A	Powerheart® G5 Kit, Auto, Norwegian-Int'l English
G5A-17C	Powerheart® G5 Kit, Auto, Norwegian-Int'l English, CPRD
G5S-17A	Powerheart® G5 Kit, Semi, Norwegian-Int'l English
G5S-17C	Powerheart® G5 Kit, Semi, Norwegian-Int'l English, CPRD
G5A-18A	Powerheart® G5 Kit, Auto, Spanish (Cat)-Int'l English
G5A-18C	Powerheart® G5 Kit, Auto, Span (Cat)-Int'l English, CPRD
G5S-18A	Powerheart® G5 Kit, Semi, Spanish (Cat) -Int'l English
G5S-18C	Powerheart® G5 Kit, Semi, Span (Cat)-Int'l Eng, CPRD
G5A-19A	Powerheart® G5 Kit, Auto, Korean-Intl ENG
G5A-19C	Powerheart® G5 Kit, Auto, KOR-Intl ENG, CPRD
G5S-19A	Powerheart® G5 Kit, Semi, KOR-Intl Eng.
G5S-19C	Powerheart® G5 Kit, Semi, KOR-Intl. Eng, CPRD

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G5A-22A	Powerheart® G5 Kit, Auto, Polish-Int'l English
G5A-22C	Powerheart® G5 Kit, Auto, Polish-Int'l English, CPRD
G5S-22A	Powerheart® G5 Kit, Semi, Polish-Int'l English
G5S-22C	Powerheart® G5 Kit, Semi, Polish-Int'l English, CPRD
G5A-23A	Powerheart® G5 Kit, Auto, Hungarian-Int'l English
G5A-23C	Powerheart® G5 Kit, Auto, Hungarian-Int'l English, CPRD
G5S-23A	Powerheart® G5 Kit, Semi, Hungarian -Int'l English
G5S-23C	Powerheart® G5 Kit, Semi, Hung -Int'l English, CPRD
G5A-25A	Powerheart® G5 Kit, Auto, Russian
G5A-25C	Powerheart® G5 Kit, Auto, Russian, ICPR
G5S-25A	Powerheart® G5 Kit, Semi, Russian/Intl Eng
G5S-25C	Powerheart® G5 Kit, Semi, Russian/Intl Eng, ICPR
G5A-26A	Powerheart® G5 Kit, Auto, Turkish-Int'l English
G5A-26C	Powerheart® G5 Kit, Auto, Turkish-Int'l English, CPRD
G5S-26A	Powerheart® G5 Kit, Semi, Turkish-Int'l English
G5S-26C	Powerheart® G5 Kit, Semi, Turkish-Int'l English, CPRD
G5A-29A	Powerheart® G5 Kit, Auto, Hebrew-Int'l English
G5A-29C	Powerheart® G5 Kit, Auto, Hebrew -Int'l English, CPRD
G5S-29A	Powerheart® G5 Kit, Semi, Hebrew -Int'l English
G5S-29C	Powerheart® G5 Kit, Semi, Hebrew -Int'l English, CPRD
G5A-31A	Powerheart® G5 Kit, Auto, Australian English
G5A-31C	Powerheart® G5 Kit, Auto, Australian English, CPRD
G5A-31A-SJA	St. John Ambulance, Auto, Australian English
G5A-31C-SJA	St. John Ambulance, Auto, Australian English, CPRD
G5A-31A-TSO	Powerheart® G5 Kit, Auto, Australian English, TSO
G5A-31C-TSO	Powerheart® G5 Kit, Auto, Australian Eng, CPRD, TSO
G5S-31A	Powerheart® G5 Kit, Semi, Australian English
G5S-31C	Powerheart® G5 Kit, Semi, Australian English, CPRD
G5S-31A-SJA	St. John Ambulance G5 Kit, Semi, Australian English
G5S-31C-SJA	St. John Ambulance G5 Kit, Semi, Australian English, CPRD
G5S-31A-TSO	Powerheart® G5 Kit, Semi, Australian English, TSO
G5S-31C-TSO	Powerheart® G5 Kit, Semi, Australian Eng, CPRD, TSO
G5A-33A	Powerheart® G5 Kit, Auto, Slovak-Int'l English
G5A-33C	Powerheart® G5 Kit, Auto, Slovak -Int'l English, CPRD
G5S-33A	Powerheart® G5 Kit, Semi, Slovak -Int'l English
G5S-33C	Powerheart® G5 Kit, Semi, Slovak-Int'l English, CPRD
G5A-34A	Powerheart® G5 Kit, Auto, THA/INTL EN
G5S-34A	Powerheart® G5 Kit, Semi, THA/INTL EN
G5A-34C	Powerheart® G5 Kit, Auto, THA/INTL EN, ICPR
G5S-34C	Powerheart® G5 Kit, Semi, THA/INTL EN, ICPR
G5A-35A	Powerheart® G5 Kit, Auto, Lithuanian-Int'l English

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G5A-35C	Powerheart® G5 Kit, Auto, Lithuanian-Int'l English, CPRD
G5S-35A	Powerheart® G5 Kit, Semi, Lithuanian-Int'l English
G5S-35C	Powerheart® G5 Kit, Semi, Lithuanian-Int'l English, CPRD
G5A-36A	Powerheart® G5 Kit, Auto, Slovenian-Int'l English
G5A-36C	Powerheart® G5 Kit, Auto, Slovenian-Int'l English, CPRD
G5S-36A	Powerheart® G5 Kit, Semi, Slovenian-Int'l English
G5S-36C	Powerheart® G5 Kit, Semi, Slovenian-Int'l English, CPRD
G5A-37A	Powerheart® G5 Kit, Auto, Cantonese-Int'l English
G5A-37C	Powerheart® G5 Kit, Auto, Cantonese-Int'l English, CPRD
G5S-37A	Powerheart® G5 Kit, Semi, Cantonese-Int'l English
G5S-37C	Powerheart® G5 Kit, Semi, Cant-Int'l English, CPRD
G5A-38A	Powerheart® G5 Kit, Auto, Serbian-Hungarian
G5A-38C	Powerheart® G5 Kit, Auto, Serbian-Hungarian, CPRD
G5S-38A	Powerheart® G5 Kit, Semi, Serbian-Hungarian
G5S-38C	Powerheart® G5 Kit, Semi, Serbian-Hungarian, CPRD
G5A-39A	Powerheart® G5 Kit, Auto, Croatian-Int'l English
G5A-39C	Powerheart® G5 Kit, Auto, Croatian-Int'l English, CPRD
G5S-39A	Powerheart® G5 Kit, Semi, Croatian-Int'l English
G5S-39C	Powerheart® G5 Kit, Semi, Croatian-Int'l English, CPRD
G5A-41A	Powerheart® G5 Kit, Auto, Ukrainian-Russian
G5A-41C	Powerheart® G5 Kit, Auto, Ukrainian-Russian, CPRD
G5S-41A	Powerheart® G5 Kit, Semi, Ukrainian-Russian
G5S-41C	Powerheart® G5 Kit, Semi, Ukrainian-Russian, CPRD
G5A-44A	Powerheart® G5 Kit, Auto, Romanian-Int'l English
G5A-44C	Powerheart® G5 Kit, Auto, Romanian -Int'l English, CPRD
G5S-44A	Powerheart® G5 Kit, Semi, Romanian -Int'l English
G5S-44C	Powerheart® G5 Kit, Semi, Romanian -Int'l Eng, CPRD
G5A-47A	Powerheart® G5 Kit, Auto, Bulgarian-Intl English
G5A-47C	Powerheart® G5 Kit, Auto, Bulgarian-Intl English, CPRD
G5S-47A	Powerheart® G5 Kit, Semi, Bulgarian-Intl English
G5S-47C	Powerheart® G5 Kit, Semi, Bulgarian-Intl English, CPRD
G5A-48A	Powerheart® G5 Kit, Auto, Catalan-Spanish IB
G5A-48C	Powerheart® G5 Kit, Auto, Catalan-Span IB, CPRD
G5S-48A	Powerheart® G5 Kit, Semi, Catalan-Spanish IB
G5S-48C	Powerheart® G5 Kit, Semi, Catalan-Spa IB, CPRD
G5A-80A	Powerheart® G5 Kit, Auto, US English-Spanish LA
G5A-80C	Powerheart® G5 Kit, Auto, US English-Spanish LA, CPRD
G5A-80C-TSO	Powerheart® G5 TSO Kit, Auto, US EN/LA ESP, CPRD
G5A-80A-TSO	Powerheart® G5 TSO Kit, Auto, US EN/LA ESP
G5S-80A	Powerheart® G5 Kit, Semi, US English-Spanish LA
G5S-80C	Powerheart® G5 Kit, Semi, US Eng/Span LA, CPRD

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Catalog Number	Description
G5S-80C-TSO	Powerheart® G5 TSO Kit, Semi, US EN/LA ESP, CPRD
G5S-80A-TSO	Powerheart® G5 TSO Kit, Semi, US EN/LA ESP
G5A-82A	Powerheart® G5 Kit, Auto, Dutch-French
G5A-82C	Powerheart® G5 Kit, Auto, Dutch-French, CPRD
G5S-82A	Powerheart® G5 Kit, Semi, Dutch-French
G5S-82C	Powerheart® G5 Kit, Semi, Dutch-French, CPRD
G5A-83A	Powerheart® G5 Kit, Auto, German-French
G5A-83C	Powerheart® G5 Kit, Auto, German-French, CPRD
G5S-83A	Powerheart® G5 Kit, Semi, German-French
G5S-83C	Powerheart® G5 Kit, Semi, German-French, CPRD
G5A-84A	Powerheart® G5 Kit, Auto, German-Italian
G5A-84C	Powerheart® G5 Kit, Auto, German-Italian, CPRD
G5S-84A	Powerheart® G5 Kit, Semi, German-Italian
G5S-84C	Powerheart® G5 Kit, Semi, German-Italian CPRD
G5A-85A	Powerheart® G5 Kit, Auto, French-Italian
G5A-85C	Powerheart® G5 Kit, Auto, French-Italian, CPRD
G5S-85A	Powerheart® G5 Kit, Semi, French-Italian
G5S-85C	Powerheart® G5 Kit, Semi, French-Italian, CPRD
G5A-90A	Powerheart® G5 Kit, Auto, US English-French Canadian
G5A-90C	Powerheart® G5 Kit, Auto, US Eng-Fr Canadian CPRD
G5S-90A	Powerheart® G5 Kit, Semi, US English-French Canadian
G5S-90C	Powerheart® G5 Kit, Semi, US Eng-Fr Canadian CPRD
G5A-92A	Powerheart® G5 Kit, Auto, RO-HUN
G5A-92C	Powerheart® G5 Kit, Auto, RO-HUN, CPRD
G5S-92A	Powerheart® G5 Kit, Semi, RO-HUN
G5S-92C	Powerheart® G5 Kit, Semi, RO-HUN, CPRD
G5A-93A	Powerheart® G5 Kit, Auto, RO-RUS
G5A-93C	Powerheart® G5 Kit, Auto, RO-RUS, CPRD
G5S-93A	Powerheart® G5 Kit, Semi, RO-RUS
G5S-93C	Powerheart® G5 Kit, Semi, RO-RUS, CPRD
G5A-27A	POWERHEART G5 KIT,AUTO,TWN/INTL EN
G5A-27C	POWERHEART G5 KIT, AUTO,TWN/INTL EN ICPR
G5S-27A	AED, G5 SEMI,PH,TWN/INTL EN
G5S-27C	POWERHEART G5 KIT,SEMI,TWN/INTL EN ICPR

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***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.


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**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).

Catalog Number	Description	Classification
XBTAED001A	Battery, Powerheart G5	Class IIb
XBTAED005A-TSO	Battery, G5 LiSO2, TSO-C142a, w/insert	Class IIb
XBTAED005A	Battery, Powerheart G5, LiSO2, TSO-C142a	Class IIb

Catalog Number	Description	Classification
XELAED001B	ELECTRODES, ADULT, G5 AED	Class IIb
XELAED001C	ELECTRODES, ADULT, G5 AED	Class IIb
XELAED002B	ELECTRODES W/CPRD, ADULT, G5 AED	Class IIb
XELAED002C	ELECTRODES W/ICPR, ADULT, G5 AED	Class IIb
XELAED003A	PEDIATRIC DEFIB PADS, POWERHEART G5	Class IIb
XELAED003C	ELECTRODES, PEDIATRIC, G5 AED	Class IIb

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