

# DECLARATION OF CONFORMITY



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



**ZOLL International Holding B.V.**  
\*Einsteinweg 8A  
6662 PW Elst, Netherlands



**ZOLL Medical Switzerland AG**  
\*\*Baarerstrasse 8  
6300 Zug, Switzerland

**Product:**      Pedi-Padz® Liquid Gel Electrode  
                    Pedi-Padz® II Electrode  
                    Pro-Padz® Radiolucent Solid Gel Electrode  
                    Pro-Padz® Radiolucent Liquid Gel Electrode  
                    Pro-Padz® Biphasic Electrode  
                    Stat-Padz® Electrode  
                    Stat-Padz® II Electrode  
                    DEP-Readiness Pack  
                    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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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 TUV SUD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany (Notified Body Number 0123).

The above products are in conformance with the provisions of Council Directive 2011/65/EU as amended on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

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

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Date

<b>Document Title:</b>		<b>ZOLL Medical Corporation</b>	
DECLARATION OF CONFORMITY, MDD, MISC. ELECTRODES MFE		269 & 271 Mill Road Chelmsford, MA 01824-4105	
<b>Page:</b> 1 of 3	<b>Document Number:</b> 9652-0083		<b>Revision:</b> V

<b>Catalog Number</b>	<b>Description</b>
8900-2061-XX	PEDI-PADZ <sup>®</sup> LIQUID GEL ELECTRODE (SINGLE)
8900-2065-XX	PEDI-PADZ <sup>®</sup> LIQUID GEL ELECTRODE (6/CASE)
8900-0810-XX	PEDI-PADZ <sup>®</sup> II ELECTRODE (ONE PAIR)
8900-0813-01	PEDI-PADZ <sup>®</sup> II, AED PLUS ELECTRODE (10 SETS)
8900-4006-XX	PRO-PADZ <sup>®</sup> RADIOLUCENT ADULT SOLID GEL ELECTRODE (SINGLE)
8900-4005-XX	PRO-PADZ <sup>®</sup> RADIOLUCENT ADULT SOLID GEL ELECTRODE (12/CASE)
8900-2106-XX	PRO-PADZ <sup>®</sup> RADIOLUCENT LIQUID GEL ELECTRODE (SINGLE)
8900-2105-XX	PRO-PADZ <sup>®</sup> RADIOLUCENT LIQUID GEL ELECTRODE (12/PACK)
8900-2302-01	PRO-PADZ <sup>®</sup> BIPHASIC ELECTRODE (SINGLE)
8900-2303-01	PRO-PADZ <sup>®</sup> BIPHASIC ELECTRODE (12/CASE)
8900-4004-XX	STAT-PADZ <sup>®</sup> ELECTRODE (SINGLE)
8900-4003-XX	STAT-PADZ <sup>®</sup> ELECTRODE (12/CASE)
8900-4008-49	STAT-PADZ <sup>®</sup> MULTI-LANGUAGE ELECTRODE (SINGLE)
8900-4003-49	STAT-PADZ <sup>®</sup> MULTI-LANGUAGE ELECTRODE (12/CASE)
8900-5001	STAT-PADZ <sup>®</sup> , ZOLL INTERNATIONAL DEFIB ELECTRODE (SINGLE)
8900-5002	STAT-PADZ <sup>®</sup> , ZOLL INTERNATIONAL DEFIB ELECTRODE (12/CASE)
8900-4018-30	DEP-READINESS PACK (SINGLE)
8900-4017-30	DEP-READINESS PACK (4-PACK)
8900-4014-30	DEP-READINESS PACK (PROPAQ MD KIT)
8900-0801-XX	STAT-PADZ <sup>®</sup> II ELECTRODE (SINGLE)
8900-0802-XX	STAT-PADZ <sup>®</sup> II ELECTRODE (12/CASE)

<b>Document Title:</b>		<b>ZOLL Medical Corporation</b> 269 & 271 Mill Road Chelmsford, MA 01824-4105
DECLARATION OF CONFORMITY, MDD, MISC. ELECTRODES MFE		
<b>Page:</b> 2 of 3	<b>Document Number:</b> 9652-0083	<b>Revision:</b> V

**\*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, 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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DECLARATION OF CONFORMITY, MDD, MISC. ELECTRODES MFE		269 & 271 Mill Road Chelmsford, MA 01824-4105
<b>Page:</b> 3 of 3	<b>Document Number:</b> 9652-0083	<b>Revision:</b> V