

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

Product: Pedi-Padz Liquid Gel Electrode
 Pedi-Padz II Electrode
 Pro-Padz Radiolucent Solid Gel Electrode
 Pro-Padz Radiolucent Liquid Gel Electrode
 Pro-Padz Cardiology Gel Electrode
 Pro-Padz Biphasic Electrode
 Stat-Padz Electrode
 Stat-Padz II Electrode
 DEP-Readiness Pack
 Cath Lab Electrode
 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 VII.

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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.

June 8, 2021

Name: Elizabeth Haines
Position: Director, Regulatory Affairs
Location: Chelmsford, MA USA

Date

Document Title: DECLARATION OF CONFORMITY, MDD, MISC. ELECTRODES MFE		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105	
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Catalog Number	Description
8900-2061-XX	PEDI-PADZ LIQUID GEL ELECTRODE (SINGLE)
8900-2065-XX	PEDI-PADZ LIQUID GEL ELECTRODE (6/CASE)
8900-000820-01	PEDI-PADZ II ELECTRODES, NO OVERBOX (SINGLE)
8900-000823-01	PEDI-PADZ II ELECTRODE, NO OVERBOX (6/CASE)
8900-0810-XX	PEDI-PADZ II ELECTRODE (ONE PAIR)
8900-0813-01	PEDI-PADZ II, AED PLUS ELECTRODE (10 SETS)
8900-4006-XX	PRO-PADZ RADIOLUCENT ADULT SOLID GEL ELECTRODE (SINGLE)
8900-4005-XX	PRO-PADZ RADIOLUCENT ADULT SOLID GEL ELECTRODE (12/CASE)
8900-000408-01	PRO-PADZ RADIOLUCENT SOLID GEL ADULT/CHILD ELECTRODE (SINGLE)
8900-000409-01	PRO-PADZ RADIOLUCENT SOLID GEL ADULT/CHILD ELECTRODE (12/CASE)
8900-2106-XX	PRO-PADZ RADIOLUCENT LIQUID GEL ELECTRODE (SINGLE)
8900-2105-XX	PRO-PADZ RADIOLUCENT LIQUID GEL ELECTRODE (12/PACK)
8900-2101-01	PRO-PADZ CARDIOLOGY W/LVP GEL ELECTRODE (SINGLE)
8900-2100-01	PRO-PADZ CARDIOLOGY W/LVP GEL ELECTRODE (12/CASE)
8900-2302-01	PRO-PADZ BIPHASIC ELECTRODE (SINGLE)
8900-2303-01	PRO-PADZ BIPHASIC ELECTRODE (12/CASE)
8900-4004-XX	STAT-PADZ ELECTRODE (SINGLE)
8900-4003-XX	STAT-PADZ ELECTRODE (12/CASE)
8900-0950-01	STAT-PADZ PROPAQ MD ELECTRODE (SINGLE)
8900-0951-01	STAT-PADZ PROPAQ MD ELECTRODE (12/CASE)
8900-000410-01	STAT-PADZ ADULT/CHILD ELECTRODE (SINGLE)
8900-000411-01	STAT-PADZ ADULT/CHILD ELECTRODE (12/CASE)
8900-4008-49	STAT-PADZ MULTI-LANGUAGE ELECTRODE (SINGLE)
8900-4003-49	STAT-PADZ MULTI-LANGUAGE ELECTRODE (12/CASE)
8900-5001	STAT-PADZ, ZOLL INTERNATIONAL DEFIB ELECTRODE (SINGLE)
8900-5002	STAT-PADZ, 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 II ELECTRODE (SINGLE)
8900-0802-XX	STAT-PADZ II ELECTRODE (12/CASE)
2110	ADAPTOR, ZOLL TO PHYSIO
2021	ADAPTOR, ZOLL TO PHILIPS
8900-2061-36	PEDI-PADZ LIQUID GEL ELECTRODE (SINGLE)
8900-2065-36	PEDI-PADZ LIQUID GEL ELECTRODE (6/CASE)

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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
Classification: Class IIb
GMDN code and term: 45806 (Multifunction cardiac electrode, adult)
42404 (Multifunction cardiac electrode, paediatric)
Scope of application: See Attached Catalog List

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:
No. QS6 079546 0021 (MDSAP Certificate)
No. Q5 079546 0029 (ISO 13485 Certificate)
No. G1 079546 0028 (EC Certificate)

Standards applied:

Conformity Standard	Description of Standard
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices -- Application of risk management to medical devices
IEC 60601-1:2006	Medical Electrical Equipment, Part 1 : General Requirements for Basic Safety and Essential Performance
EN 60601-1-2:2007	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
EN 60601-2-4:2010	Medical Electrical Equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
CISPR11/EN 55011:2009	Industrial, scientific and medical equipment – radio-frequency disturbance characteristics – limits and methods of measurement
ANSI/AAMI EC12:2000	Disposable ECG electrodes
EN 61000-4-3:2006	Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
BS EN ISO 11137-1:2006	Sterilization of healthcare products-radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
ISO 11137-2:2006	Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose
ISO 11137-3:2006	Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects
ISO 11737-1:2006	Sterilization of medical devices-Microbiological methods-Part 1: Determination of a population of microorganisms on products
ISO 11737-2:1998	Sterilization of medical devices-Microbiological methods-Part 2: Tests of sterility performed in the validation of a sterilization process

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FULL QUALITY ASSURANCE PROCEDURES

Conformity Standard	Description of Standard
BS EN 552:1994	Sterilization of medical devices-Validation and routine control of sterilization by irradiation
BS EN 556-1:2001	Sterilization of medical devices- Requirements for medical devices to be designated 'Sterile'-Part 1: Requirements for terminally sterilized medical devices
EN ISO 10993-1:2009/AC:2010	Biological Evaluation of Medical Devices – Part 1: Evaluation And Testing
EN ISO 10993-5:2009/(R)2014	Biological Evaluation of Medical Devices – Part 5: Test For In Vitro Cytotoxicity
EN ISO 10993-10:2010	Biological Evaluation of Medical Devices – Part 10: Test For Irritation and skin sensitization
MIL STD 810G:2008	Environmental engineering consideration and laboratory test (loose cargo vibration test)
ISTA 3A:2008/2013	Packaging – shipping test
EN ISO 15223:2016	Symbols to be used with medical device labels, labelling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices
MEDDEV 2.7.1: 2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies

CATALOG LIST

Catalog Number	Description
8900-2061	PEDI-PADZ MULTI-FUNCTION ELECTRODE (SINGLE)
8900-2065	PEDI-PADZ MULTI-FUNCTION ELECTRODE (6/CASE)
8900-2061-36	PEDI-PADZ LIQUID GEL ELECTRODE (SINGLE)
8900-2065-36	PEDI-PADZ LIQUID GEL ELECTRODE (6/CASE)
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8900-4005-XX	PRO-PADZ RADIOLUCENT ADULT SOLID GEL ELECTRODE (12/CASE)
8900-000408-01	PRO-PADZ RADIOLUCENT SOLID GEL ADULT/CHILD ELECTRODE (SINGLE)
8900-000409-01	PRO-PADZ RADIOLUCENT SOLID GEL ADULT/CHILD ELECTRODE (12/CASE)
8900-2106-XX	PRO-PADZ RADIOLUCENT LIQUID GEL ELECTRODE (SINGLE)
8900-2105-XX	PRO-PADZ RADIOLUCENT LIQUID GEL ELECTRODE (12/PACK)
8900-2101-01	PRO-PADZ CARDIOLOGY W/LVP GEL ELECTRODE (SINGLE)
8900-2100-01	PRO-PADZ CARDIOLOGY W/LVP GEL ELECTRODE (12/CASE)
8900-2302-01	PRO-PADZ BIPHASIC ELECTRODE (SINGLE)
8900-2303-01	PRO-PADZ BIPHASIC ELECTRODE (12/CASE)
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8900-4003-XX	STAT-PADZ ELECTRODE (12/CASE)
8900-0950-01	STAT-PADZ PROPAQ MD ELECTRODE (SINGLE)

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8900-000411-01	STAT-PADZ ADULT/CHILD ELECTRODE (12/CASE)
8900-4008-49	STAT-PADZ MULTI-LANGUAGE ELECTRODE (SINGLE)
8900-4003-49	STAT-PADZ MULTI-LANGUAGE ELECTRODE (12/CASE)
8900-5001	STAT-PADZ, ZOLL INTERNATIONAL DEFIB ELECTRODE (SINGLE)
8900-5002	STAT-PADZ, 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)
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2110	ADAPTOR, ZOLL TO PHYSIO
2021	ADAPTOR, ZOLL TO PHILIPS

June 8, 2021

Elizabeth Haines, Director, Regulatory Affairs

Date

Name, Position

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