Digitally signed by Ceaicovschi Tudor
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Location: Moldova

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

Product: Pedi-Padz Solid Gel Electrode
Pedi-Padz Radiolucent Solid Gel Electrode
See below for catalog list

Catalog Number	Description
8900-3001-XX	PEDI-PADZ SOLID GEL ELECTORDES (SINGLE)
8900-3000-XX	PEDI-PADZ SOLID GEL ELECTRODES (6/CASE)
8900-2500-01	PEDI-PADZ SOLID GEL W/10FT WIRES ELECTRODES (SINGLE)
8900-2501-01	PEDI-PADZ SOLID GEL W/10FT WIRES ELECTRODES (6/CASE)
8900-1007-XX	PEDI-PADZ RADIOLUCENT SOLID GEL ELECTRODES (SINGLE)
8900-1005-XX	PEDI-PADZ RADIOLUCENT SOLID GEL ELECTRODES (6/ CASE)

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.

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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 of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

Elizabeth McMeniman
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Date: 2019.09.18 09:48:51 -04'00'

Elizabeth McMeniman
Director, Regulatory Affairs

September 18, 2019
Date

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 01824-4105 USA

Medical device(s): Pedi-Padz Solid Gel electrodes
Pedi- Padz Radiolucent Solid Gel electrodes

Classification: Class IIb

GMDN code and term: 42404 (Multifunction cardiac electrode, paediatric)

Scope of application: Pedi-Padz Solid Gel electrodes
Pedi- Padz Radiolucent Solid Gel electrodes
See the 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***
No. Q5 079546 0020
No. G1 079546 0023

Standards applied:

Conformity Standard	Description of Standard
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	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
BS EN 552:1994	Sterilization of medical devices-Validation and routine control of sterilization by irradiation

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURES

Conformity Standard	Description of Standard
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)
MEDDEV 2.7.1: 2016	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
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

CATALOG LIST

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Elizabeth McMeniman

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Date: 2019.09.18 09:48:35 -04'00'

Signature

Elizabeth McMeniman, Director, Regulatory Affairs
Name, Position

September 18, 2019
Date