Declaration of Conformity

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EC REP

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We herewith declare that the products detailed within this declaration meet the requirements and provisions of the EU Medical Device Regulation 2017/745 and Switzerland's Medical Device Ordinance (MedDO) of 1 July 2020. All supporting documentation is retained on the premises of ZOLL Medical Corporation. ZOLL Medical Corporation assumes responsibility for compliance with the requirements of Regulation (EU) 2017/745, MedDO, and all other Union legislation applicable to the device.

The products detailed within this declaration 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provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which was repealed by Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE).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, these products are in conformance with the provisions of Directive 2012/19/EU.

In addition, the products listed herein 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.

Single Registration Number (SRN)	US-MF-000021386 - Manufacturer
Single Registration Number (SRN)	NL-AR-000012554 – EU Rep
Basic UDI-DI	See Attachment 1
ISO 13485:2016 Certificate Details	Certificate #: Q5 079546 0029, Rev. 01 Effective Date: 2024-06-02 Expiry Date: 2027-06-01 ISO Registrar: TÜV SÜD Product Service GmbH
EC Certificate Details	N/A
Devices: REF Numbers/Risk Classification/Rule	See Attachment 1
Harmonized Standards	See “General Safety and Performance Requirements Checklist”
Common Specifications	N/A

For and on behalf of
ZOLL Medical Corporation

Natalie England

Digitally signed by Natalie England
Date: 2024.05.07 18:18:21 +01'00'

Name: Natalie England
Position: Director, Regulatory Affairs
Location: Chelmsford, MA 01824-4105 USA

Date:

Attachment 1:

Device REF Numbers / Risk Classification / Rule

REF	Description	Risk Class	Rule	Intended Purpose
Device: CPR Uni-padz (Basic UDI-DI 08479460KSZ)				
8900-000280	CPR-Uni-padz III	Class I	Rule 13	To deliver defibrillation therapy to the heart and provide CPR assistance/feedback and ECG monitoring.
Device: CPR Dura-padz (Basic UDI-DI 08479460GSR)				
8900-000310	CPR Dura-Padz, Reusable Defibrillation Electrode	Class I	Rule 13	To deliver defibrillation, cardioversion therapy to the heart and provide CPR assistance/feedback and ECG monitoring.
Device: CPR D-padz (Basic UDI-DI 08479460JSX)				
8900-000407-01	CPR-D-padz Adult/Child Electrode	Class I	Rule 13	To deliver defibrillation therapy to the heart and provide CPR assistance/feedback and ECG monitoring.
8900-0800-01	CPR-D-padz One Piece Electrode Pad with Real CPR Help	Class I	Rule 13	To deliver defibrillation therapy to the heart and provide CPR assistance/feedback and ECG monitoring.
8900-0815-01	CPR-D-padz Electrodes, without Accessory Kit	Class I	Rule 13	To deliver defibrillation therapy to the heart and provide CPR assistance/feedback and ECG monitoring.
Device: CPR Stat-padz (Basic UDI-DI 08479460ACBF)				
8900-0400	CPR Stat-padz (8 per case)	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-0402	CPR Stat-padz (individual)	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
Device: OneStep CPR Adult Electrodes (Basic UDI-DI 08479460HST)				
8900-0223-01	OneStep CPR Resuscitation Electrode, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-0213-01	OneStep CPR Resuscitation Electrode, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.

REF	Description	Risk Class	Rule	Intended Purpose
8900-000350-01	OneStep CPR II Resuscitation Electrode, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-000351-01	OneStep CPR II Resuscitation Electrode, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-0224-01	OneStep Complete Resuscitation Electrode, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-0214-01	OneStep Complete Resuscitation Electrode, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-000405-01	OneStep CPR Complete Adult/Child Electrode, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-000406-01	OneStep CPR Complete Adult/Child Electrode, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-0225-01	OneStep CPR A/A Resuscitation Electrode, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-0217-01	OneStep CPR A/A Resuscitation Electrode, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-000251-05	OneStep CPR A/A Electrode with Green Connector, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-000254-05	OneStep CPR A/A Electrode with Green Connector, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
Device: OneStep Pediatric CPR Electrodes (Basic UDI-DI 08479460HST)				
8900-000219-01	OneStep Pediatric CPR Electrodes, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.

REF	Description	Risk Class	Rule	Intended Purpose
8900-000220-01	OneStep Pediatric CPR Electrodes, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-000380-01	OneStep Pediatric CPR Electrode, Single	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
8900-000381-01	OneStep Pediatric CPR Electrode, 8/Case	Class I	Rule 13	Intended for ECG monitoring and for delivering defibrillation, cardioversion, Noninvasive pacing and CPR assistance/feedback.
Device: Powerheart G5 Electrodes (Basic UDI-DI 08479460ANC5)				
XELAED002B	Electrodes w/CPRD, Adult, G5 AED	Class I	Rule 13	To deliver defibrillation therapy to the heart and provide CPR assistance/feedback
XELAED002C	Electrodes w/ICPR, Adult, G5 AED	Class I	Rule 13	To deliver defibrillation therapy to the heart and provide CPR assistance/feedback.

As we implement label changes with respect to new MDR requirements these will be reflected on all applicable labelling.