

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: CPR Uni-Padz®, Electrode
CPR Uni-Padz®, Electrode (*U.S only*)
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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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.

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

Date

Catalog Number	Description
8900-000280	CPR Uni-Padz®, Electrode
8900-000280-01	CPR Uni-Padz®, Electrode (U.S only)

Document Title: DECLARATION OF CONFORMITY, MDD, CPR UNI-PADZ		ZOLL Medical Corporation 269 & 271 Mill Road Chelmsford, MA 01824-4105
Page: 1 of 2	Document Number: 9652-000133	Revision: M

***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.

Document Title:		ZOLL Medical Corporation	
DECLARATION OF CONFORMITY, MDD, CPR UNI-PADZ		269 & 271 Mill Road Chelmsford, MA 01824-4105	
Page:	Document Number:		Revision:
2 of 2	9652-000133		M