

DECLARATION OF CONFORMITY

zoll

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

ZOLL International Holding B.V.

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Product Description	Classification	Rule	Annex
Pedi-padz [®] Multi-Function Electrodes	I	1	IX
Pedi-padz II Multi-Function Electrodes	I	1	IX
Pro-padz [®] Cardiology Specialty Multi-Function Electrodes	I	1	IX
Pro-padz Biphasic Multi-Function Electrodes	I	1	IX
Pro-padz Radiolucent Multi-Function Electrodes	I	1	IX
Stat-padz® Adult Multi-Function Electrodes	I	1	IX
Stat-padz II Multi-Function Electrodes	I	1	IX
Multi-Function Electrodes	I	1	IX
ECG Monitoring Electrodes	I	1	IX

ZOLL declares that the above products conform to European Council Directive 93/42/EEC (Medical Device Directive) class I per rule 1 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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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 13485:2012 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.

23 May 2016

Paul Dias

Vice President, QA & RA