



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:

ZOLL X Series®

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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 13485:2012/AC:2012 certified by the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany (Notified Body Number 0123).

The above products are in conformance with the provisions of Council Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment which apply to them.

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.

2 February 2016

Paul Dias
Vice President, QA & RA

Annex to Declaration of Conformity Accessory List

ZOLL declares that the products listed below conform to European Council Directive 93/42/EEC (Medical Device Directive). Device Classifications are shown next to each product listed as follows: Class I (I), Class I Sterile (IS), Class IIa (IIa), Class IIb (IIb). The MDD Classification Rule used, and the MDD Annex under which the products are assessed, are also indicated.
(X represents any numeric digit)

ECG Accessories	REF	Class/Rule/Annex	SpO2 Accessories, cont.	REF	Class/Rule/Annex
ECG, 3-Lead Cable, AAMI/ IEC	8300-0800-01, -12	1 / 1 / VII	Rainbow Patient Cable	8000-0330, -0331, -0341, -0342	1 / 1 / VII
ECG, 5-Lead Cable, AAMI/ IEC	8300-0801-01, -12	1 / 1 / VII			
ECG, 12-Lead "Breakaway" Cable, AAMI/ IEC	8300-0802-01, -12	1 / 1 / VII	Rainbow Reusable Cable / Sensor	8000-0377	IIb / 10 / II
ECG, 4-Lead "Breakaway" Trunk				8000-0332, -0333, -0334, -0335, -0343, -0344, -0345, -0346	IIb / 10 / II
Cable and 4 lead wire set only, AAMI/ IEC	8300-0803-01, -12	1 / 1 / VII		8000-00146X	IIb / 10 / II
ECG, Detachable 6 precordial lead wire set for "Breakaway" 12-Lead Patient Cable, AAMI/ IEC	8300-0804-01, -12	1 / 1 / VII		8000-000467	IIb / 10 / II
				8000-000371	IIb / 10 / II
CO2 Accessories (Oridion Filterlines)			Temperature Accessories		
EtCO2 Smart CapnoLine Plus	8300-0524-01	1 / 2 / VII	YSI Reusable Adult, Skin Probe	8000-0670	IIa / 10 / II
	8300-0525-01	1 / 2 / VII	YSI Reusable Pediatric, Skin Probe	8000-0671	IIa / 10 / II
EtCO2 FilterLines	8300-0521-01	1 / 1 / VII	YSI Reusable Adult, Esophageal/Rectal	8000-0668	IIa / 10 / II
	8300-0522-01	1 / 1 / VII	YSI Reusable Pediatric, Esophageal/Rectal	8000-0669	IIa / 10 / II
	8300-0520-01	1 / 1 / VII	Sensor Adapter Cable for Disposable Probes	8000-0674	IIa / 10 / II
EtCO2 VitaLine	8300-0523-01	1 / 1 / VII	YSI Disposable Esophageal/Rectal Probe	8000-0672	IIa / 10 / II
			YSI Disposable Skin Probe	8000-0673	IIa / 10 / II
NIBP Accessories			Defibrillation Accessories		
NIBP Hose	8300-0796-01	1 / 1 / VII	X Series Multifunction Therapy Cable	8300-0783	1 / 1 / VII
	8300-0002-01	1 / 1 / VII	M Series External Paddles set with controls and built-in pediatric electrodes	8000-1010-XX	1 / 1 / VII
Disposable Neonatal Cuff	8300-0797-01	1 / 1 / VII	ZOLL Sterilizable Internal Handle with Switch, 10' cable (1.0", 1.6", 2.0", 2.7", 3.0" spoon sizes)	8011-0139-XX	IIb / 9 / II
	5082-101-1	1 / 1 / VII	ZOLL Sterilizable Internal Handle, without Switch, 10' cable (1.0", 1.6", 2.0", 2.7", 3.0" spoon sizes)	8011-0140-XX	IIb / 9 / II
	5082-102-1	1 / 1 / VII	ZOLL Defibrillation Gel	002051-U	1 / 1 / VII
	5082-103-1	1 / 1 / VII	ZOLL OneStep cable	8300-000676	1 / 1 / VII
	5082-104-1	1 / 1 / VII	Electrodes, CPR stat-padz	8900-0400;	IIb / 9 / II
	5082-105-1	1 / 1 / VII		8900-0402	IIb / 9 / II
Reusable Cuffs	8000-0895	1 / 1 / VII	Electrode, pedi-padz II	8900-000820-01;	1 / 1 / VII
	REUSE-07-2MQ	1 / 1 / VII		8900-000823-01	1 / 1 / VII
	REUSE-08-2MQ	1 / 1 / VII	Electrodes, OneStep Basic	8900-0039-01	1 / 1 / VII
	REUSE-09-2MQ	1 / 1 / VII		8900-0221-01	1 / 1 / VII
	REUSE-10-2MQ	1 / 1 / VII	Electrodes, OneStep Pacing	8900-0211-XX	1 / 1 / VII
	REUSE-11-2MQ	1 / 1 / VII		8900-0222-01	1 / 1 / VII
	REUSE-11L-2MQ	1 / 1 / VII	Electrodes, OneStep CPR	8900-0212-01	1 / 1 / VII
	REUSE-12-2MQ	1 / 1 / VII		8900-0223-XX	IIb / 9 / II
	REUSE-12L-2MQ	1 / 1 / VII	Electrodes, OneStep Complete	8900-0213-XX	IIb / 9 / II
	REUSE-13-2MQ	1 / 1 / VII		8900-0224-XX	IIb / 9 / II
			Electrodes, OneStep CPR AA, Single	8900-0214-XX	IIb / 9 / II
IBP Accessories				8900-0225-01	IIb / 9 / II
Transducer Interface cable	8300-0788-01	1 / 1 / VII	Electrodes, OneStep Pediatric (1 PAIR)	8900-0217-01	IIb / 9 / II
	8300-0787-01	1 / 1 / VII	Electrodes, CPR-D*padz One piece	8900-0215-01	1 / 1 / VII
			Electrodes, CPR-D-padz w/o Accessory Kit	8900-0800-XX	IIb / 9 / II
SpO2 Accessories			Electrodes, Stat-padz	8900-0815-XX	IIb / 9 / II
LNCS Reusable Sensors	8000-0294, -0295, -0379	IIb / 10 / II		8900-0951-01	1 / 1 / VII
LNCS Disposable Sensors	8000-032X	IIb / 10 / II		8900-0950-01	1 / 1 / VII
LNCS Reusable Cable	8000-0293, -0298	1 / 1 / VII			
LNCS/LNOP Cables	8000-0325, -0326, -0327	1 / 1 / VII			
LNOP Reusable sensor and cable	8000-0296	IIb / 10 / II			
Rainbow Single use sensor	8000-0336, -0337	IIb / 10 / II			
	8000-0339, -0340	IIb / 10 / II			
	8000-000475, -000476, -000477, -000478	IIb / 10 / II			
	8000-000462	IIb / 10 / II			
	8000-001463	IIb / 10 / II			
	8000-000468, -000469	IIb / 10 / II			

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Other Accessories

CPRD-to-MFC Connector	1005-0100	1 / 1 / VII
ZOLL SurePower II Rechargeable Battery	8000-0580-01	1 / 1 / VII
SurePower Charger Station	8050-0030-XX	1 / 1 / VII
SurePower II Battery Charger-		
X Series Battery Adapter	8300-0250-XX	1 / 1 / VII
Single Bay Charger	8200-000100-XX	1 / 1 / VII
AutoPulse Adapter Assy	8000-000515-40	1/ 1/ VII

Non-Medical Device Accessories

Auxiliary Power Adapter,	8300-0004	
Replacement Power Cord – U.S.	8000-0100	
DC Auxiliary Power Supply	3007-000006	
	8300-000006	
X Series Soft Carrying Case	8707-000501-01	
ECG 80 mm Chart Recorder Paper	8000-000901	
USB Communications Cable	8707-000500-01	
USB Adapter	8000-000383	