

ZOLL®	DOCUMENT NUMBER: EDC-2846	REVISION: 01	PAGE: 1 OF 4
DECLARATION OF CONFORMITY – AUTOPULSE RESUSCITATION SYSTEM MODEL 100 AND ACCESSORIES			

Declaration of Conformity

Manufacturer: ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131
USA

Product Description: AutoPulse® Resuscitation System Model 100 and Accessories
(See attached product list)

Applicable Directive: Council Directive 93/42/EEC Concerning Medical Devices

Classification: Class IIb, Rule 9 per Annex IX of the MDD

Route to Conformity: MDD Annex II

Notified Body: DEKRA Certification B.V. (CE 0344)
Meander 1051, Postbus 5185
6825 MJ, 6802 ED
Arnhem, The Netherlands

EU Authorized Representative: ZOLL International Holding B.V.
Newtonweg 18
6662 PV ELST
The Netherlands

Certificates: CE Marking of Conformity Certificate: 2028431CE01
Quality System Certificate: 560161

Declaration: We hereby declare that the products listed conform to the EC Council Directive 93/42/EEC Concerning Medical Devices. This is based on the Certificates listed above in accordance with Annex II of the EC-Directive provided by DEKRA Certification B.V.



Sam Nanavati
Vice President,
Quality Assurance and Regulatory Affairs

09/17/2015

Date

ZOLL®	DOCUMENT NUMBER: EDC-2846	REVISION: 01	PAGE: 2 OF 4
DECLARATION OF CONFORMITY – AUTOPULSE RESUSCITATION SYSTEM MODEL 100 AND ACCESSORIES			

Attachment – Product List

Autopulse Resuscitation System (Class IIb) and Accessories

AutoPulse

ZOLL Item Number	ZOLL Circulation Part Number	Description	Initial Certification Date
8700-0700-XX	11486-XXX	AutoPulse 1.5G	November 26, 2003
8700-0730-XX	11574-XXX	AutoPulse 1.5G Pass-Thru	
8700-0740-XX	11807-XXX	AutoPulse 1.5G Load Signal	
8700-0700-XX-66	10678-XXX	AutoPulse 1.0G, Refurb	
	11947-XXX	AutoPulse 1.5G, Refurb	
8700-0730-XX-66	12059-XXX	AutoPulse 1.5G Pass-Thru, Refurb	
8700-0740-XX-66	12060-XXX	AUTOPULSE Load Signal, Refurb	

Battery & Charger

ZOLL Item Number	ZOLL Circulation Part Number	Description	Initial Certification Date
8700-0702-XX	10627-XXX	NiMH Battery	November 26, 2003
8700-0703-XX*	10630-XXX	NiMH Battery Charger	
8700-0753-XX	12441-001	Multi-Chemistry Battery Charger	
8700-0752-XX	12742-001	Lithium-Ion Battery	
8700-000760-01	12743-001	AutoPulse Sure Power Charger & Battery Kit (includes 3 NiMH Batteries & a Multi-Chemistry Battery Charger)	

LifeBand

ZOLL Item Number	ZOLL Circulation Part Number	Description	Initial Certification Date
8700-0701-XX	11126-XXX	LifeBand, Single-Pack	November 26, 2003
8700-0706-XX	11130-XXX	LifeBand 3-Pack	

AutoPulse Language Variants

ZOLL Item Number -XX	ZOLL Circulation Part Number -0XX	Language
-01	-001	English
-08	-002	German

ZOLL®	DOCUMENT NUMBER: EDC-2846	REVISION: 01	PAGE: 3 OF 4
DECLARATION OF CONFORMITY – AUTOPULSE RESUSCITATION SYSTEM MODEL 100 AND ACCESSORIES			

ZOLL Item Number -XX	ZOLL Circulation Part Number -0XX	Language
-02	-003	French
-16	-004	Dutch
-11	-005	Italian
-10	-006	Spanish
-20	-008	Norwegian
-24	-009	Portuguese
-22	-010	Swedish
-21	-011	Finnish
-27	-012	Danish
-04	-015	Polish
-17	-017	Czech

ZOLL®	DOCUMENT NUMBER: EDC-2846	REVISION: 01	PAGE: 4 OF 4
DECLARATION OF CONFORMITY – AUTOPULSE RESUSCITATION SYSTEM MODEL 100 AND ACCESSORIES			

Revision History

Rev.	Description	Originator
01	Initial Release	R. Kimura