

Declaration of Conformity

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

Product Description AutoPulse® Resuscitation System Model 100
AutoPulse® Resuscitation System Model 100 with Pass Through Connectors
AutoPulse® Resuscitation System Model 100 with Pass Through Connectors, EV
AutoPulse® Plus Resuscitation System
Accessories
See attached list, applicable to products manufactured on or after November 27, 2003

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

Classification: Class IIb, per Rule 9 AutoPulse & LifeBand
Class IIa per Rule 9, Battery & Battery Charger

Route to Conformity: Annex II

Key Standards Used ISO 13485
ISO 14971
IEC 60601 Series

Notified Body: DEKRA Certification B.V.
CE 0344

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 & Regulatory Affairs

12/23/2013
Date



Annex to Declaration of Conformity (Product List)

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	11574-001	AutoPulse 1.5G Pass-Thru, ENG	
8700-0730-XX-66	12059-XXX	AutoPulse 1.5G Pass-Thru, ENG, Refurb	
8700-0700-XX-66	11391-XXX	AutoPulse 1.1G, Refurb	
	11947-001	AutoPulse 1.5G, Refurb	
8700-0740-XX	11807-XXX	AutoPulse 1.5G Load Signal	
8700-0780-XX	12870-XXX	AUTOPULSE PASS-THRU EV	

Battery & Charger

ZOLL Item Number	Zoll Circulation Part Number	Description	Initial Certification Date
8700-0702-XX	10627-XXX	Battery	November 26, 2003
8700-0702-XX-66	11401-001	Battery, Refurb, ENG	
8700-0703-XX*	10630-XXX	Charger	
8700-0703-XX-66*	11393-001	Charger, Refurb, ENG	
8700-0753-XX	12441-001	Multi-Chemistry Battery Charger	
8700-0752-XX	12508-001	Lithium-Ion Battery	

*8700-0703-XX and 8700-0703-XX-66 will not be sold in the EU after June 1, 2012, since they are not compliant to the third edition of IEC 60601-1. ZOLL will continue to offer service for both model numbers already in use.

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	Device Language
-01	-001	English
-08	-002	German
-02	-003	French
-16	-004	Dutch
-11	-005	Italian
-10	-006	Spanish
-20	-008	Norwegian
-22	-010	Swedish
-21	-011	Finnish
-27	-012	Danish