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DOCUMENT ID:
EDC-2846

**DECLARATION OF CONFORMITY – AUTOPULSE RESUSCITATION
SYSTEM MODEL 100 AND ACCESSORIES**

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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



EC REP

ZOLL International Holding B.V.
*Einsteinweg 8A, 6662 PW ELST, The Netherlands

CH REP

ZOLL Medical Switzerland AG
**Baarerstrasse 8
6300 Zug, Switzerland



Procamed AG
Schulstrasse 5, CH-8355 Aadorf, Switzerland

Certificates: CE Marking of Conformity Certificate: 2028431CE01
Quality System Certificate: 3821343 (ISO/EN ISO 13485:2016)
Quality System Certificate: 3825099 (MDSAP ISO 13485:2016)


Declaration: We hereby declare that the products listed conform to the EC Council Directive 93/42/EEC Concerning Medical Devices and Switzerland's Medical Device Ordinance (MedDO) of 1 July 2020. This is based on the Certificates listed above in accordance with Annex II of the EC-Directive provided by DEKRA Certification B.V.

In addition, the products listed are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Chelmsford, MA, USA
Place of signature

Daniel Connell
Manager, Regulatory Affairs

May 17, 2023
Date

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***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
 The Netherlands

As we implement this address change it will be reflected on all applicable product labelling.

****Swiss Authorized Representative (CH-REP) Address Change**

Please note a change to ZOLL’s Swiss Authorized Rep address:

Previous Address:

ZOLL Medical Switzerland AG
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 all applicable product labelling.



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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	
8700-0780-XX	12870-XXX	AutoPulse 1.5G Pass-Thru EV	
8700-0740-XX	11807-XXX	AutoPulse 1.5G Load Signal	
8700-00876-XX	13423-XXX	AutoPulse 1.5G Load Signal EV	
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
8700-0753-XX	12441-001	Multi-Chemistry Battery Charger	November 26, 2003
8700-0752-XX	12742-001	Lithium-Ion Battery	
	13650-XXX	Lithium-Ion Battery, 30% Charge	
8700-000765-01	12759-001	AutoPulse Sure Power Charger & Li-ion Battery Kit, USA (includes 3 Li-ion 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	



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AutoPulse Language Variants

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

AutoPulse Accessories

ZOLL Item Number	ZOLL Circulation Part Number	Description
8700-000758-01	12639-001	Soft Carry Case, with pocket
8700-0708-XX	10877-XXX	Grip Strip Set
8700-0709-XX	11028-XXX	Shoulder Restraint
8700-0710-XX	11035-XXX	Head Immobilizer, 5-Pack
8700-0711-XX	10999-XXX	Cable Ties
8700-000880-01	11194-003	Hospital Transporter, AutoPulse, R Series
8700-0717-01	11364-001	Hygiene Barrier

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Revision History

Rev.	Description	Originator	Effective Date
01	Initial Release	R. Kimura	9/18/2015
02	Added Li-ion battery, 30% charge Updated AutoPulse Sure Power Charger & Battery Kit from NiMH battery kit to Li-ion battery kit	J. Gendler	8/12/2016
03	Added AutoPulse 1.5G Load Signal EV and include statement of RoHS compliance per SOP5-023	J. Gendler	10/6/2017
04	Added a table for AutoPulse Accessories, which is also included in the technical file EDC-1698 Rev. 06.	Y. Enrile	8/31/2018
05	<ul style="list-style-type: none"> Reformatted document Added AutoPulse 1.5 Pass-Thru EV model to products list Added Place of Declaration 	Harini Raghavan	7/1/2019
06	<ul style="list-style-type: none"> Updated reference to ISO 13485:2016 Certificate Added reference to MDSAP ISO 13485:2016 Certificate Deleted reference to NiMH Battery under products list table Deleted reference to Transporter (8700-0716-01) and replaced with the new hospital transporter (8700-000880-01) 	Harini Raghavan	11/26/2019
07	<ul style="list-style-type: none"> Added Legal Importer symbol and address Replace text for AR with the EC AR symbol 	Harini Raghavan	05/14/2021
08	<ul style="list-style-type: none"> Corrected the header per ZOLL Circulation format Added document release date under document history block for revision 7. 	Harini Raghavan	06/07/2021
09	<ul style="list-style-type: none"> Addition of Swiss authorized representative (CH REP) and language added to reflect compliance to Swiss MEDDO 	Riki Chaudhary	12/21/2021
10	<ul style="list-style-type: none"> Added importer address (Procamed AG) for Switzerland to reflect compliance to Swiss MEDDO 	Riki Chaudhary	1/17/2022
11	<ul style="list-style-type: none"> Updated importer address (Procamed AG) Minor Formatting changes 	Paige Johnson	09/29/2022
12	<ul style="list-style-type: none"> EC Representative Address Change updates: <ul style="list-style-type: none"> Updated address on page 1 Added language to explain the rollout of label changes 	Paige Johnson	10/27/2022
13	<ul style="list-style-type: none"> Swiss Rep Address Change updates: <ul style="list-style-type: none"> Updated address on page 1 Added language to explain the rollout of label changes Removed Quick Case and Soft Stretcher from the list of accessory part numbers as these are Class I devices 	Paige Johnson	See Signature Page

Signatures

Creech, Jeffrey

Document ID: EDC-2846
Revision: 13
Electronically signed by Creech, Jeffrey
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Reason: Approval of Document

Mitchell, Mark

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Date: 6/2/2023 10:30:59 AM
Reason: Approval of Document

Harmon, Hal

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Date: 6/2/2023 12:38:17 PM
Reason: Approval of Document

Mai, Thomas

Document ID: EDC-2846
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Date: 6/2/2023 4:17:22 PM
Reason: Approval of Document

Lam, Doug

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Electronically signed by Lam, Doug
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Reason: Approval of Document

Johnson, Paige

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