# EC CERTIFICATE

Number: **2028431CE01**

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**
(Devices in Class IIa, IIb or III)

Manufacturer:

**ZOLL Circulation, Inc.**
**2000 Ringwood Avenue**
**San Jose, CA 95131**
**United States Of America**

For the product category(ies)

**Automated Cardiac Resuscitation Device**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents that form the basis of this certificate:

**Certification Notice 2028431CN, initially dated 26 November 2003**
**Addendum, initially dated 26 November 2003**

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

Digitally signed by Ceaicovschi Tudor
Date: 2023.11.17 01:19:32 EET
Reason: MoldSign Signature
Location: Moldova

This certificate is valid until: **26 May 2024**
Issued for the first time: 26 November 2003
Revised: 17 January 2014
Reissued: 1 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager



DEKRA Certification B.V. is Notified Body with ID no 0344

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# ADDENDUM

Belonging to certificate: **2028431CE01** 

# CE MARKING OF CONFORMITY
## MEDICAL DEVICES

**Automated Cardiac Resuscitation Device**

Issued to:

**ZOLL Circulation, Inc.**
**2000 Ringwood Avenue**
**San Jose, CA 95131**
**United States Of America**

This certificate covers the following product(s):

AutoPulse® Resuscitation System Model 100 and Accessories (Class IIb)

Initial date: 26 November 2003
Revision date: 22 November 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager



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