ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 16 06 79546 016

Manufacturer:
ZOLL Medical Corporation
269 Mill Road
Chelmsford MA 01824-4105
USA

EC-Representative:
Zoll International Holding B.V.
Newtonweg 18
6662 PV Elst
THE NETHERLANDS

Product Category(ies):
External Defibrillators, Automatic External Defibrillators, Defibrillation Electrodes, Infusion Pumps with Blood Cartridge and Crystalloid/Colloid Cartridge, Portable Ventilators with Patient Breathing Circuits.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72108819

Valid from: 2016-06-15
Valid until: 2021-03-07

Date, 2016-06-15

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Digitally signed by Ermicev Alexandr
Date: 2019.07.11 18:32:21 EEST
Reason: MoldSign Signature
Location: Moldova

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Facility(ies):

ZOLL Medical Corporation
269 Mill Road, Chelmsford MA 01824-4105, USA

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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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