TÜVRheinland®

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60036884 0001

Report No.: 31092646 001

Manufacturer:
Zoll Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford MA 01824-4105
USA

Scope:
Design/Development and Manufacture of Monitors and Cardiac Resuscitation Devices

(see attachment for products and sited included)

Replaces Approval, Registration No.: HD 60021607 0001

Date of Expiry: 07.03.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 08.03.2011

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HD 60036884 0001
Report No.: 31092646 001

Manufacturer:

Zoll Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford MA 01824-4105
USA

Scope:

Products:

- External Defibrillators
  Models: M Series, E series, R Series

- Automatic External Defibrillators
  Models: AED Plus, AED PRO, AED 10

- sterile Defibrillation Electrodes

sites included:

Zoll Medical Corporation, 271 Mill Road,
Chelmsford, MA 01824

Zoll Chicago, 2 Corporate Drive, Suite 110,
Long Grove, IL 60047

Certification Body:

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. D. Meier

Date 08.03.2011