TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60091000 0001

Report No.: 31291366 001

Manufacturer:
Defibtech, L.L.C.
741 Boston Post Road, Suite 201
Guilford CT 06437
USA

Products:
External Defibrillators

Products and Facilities: see attachment

Replaces Approval, Registraion No. : HD 60026981 0001

Expiry Date: 2018-11-07

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2013-12-19

Date: 2013-12-19

Notified Body

TÜV Rheinland LGA Products GmbH

TÜVRheinland

Jürgen Welte

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60091000 0001
Report No.: 31291366 001

Manufacturer: Defibtech, L.L.C.
741 Boston Post Road, Suite 201
Guilford CT 06437
USA

Facilities:
Defibtech, L.L.C.
4 Progress Avenue
Seymour, CT 06437 USA
Scope: Activities related to Manufacturing

Products:
- Semi-automatic External Defibrillators
- Fully-automatic External Defribillators

Notified Body

Date: 2013-12-19

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Jürgen Welte