EC Certificate

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

TÜVRheinland®

Registration No.: HD 60133912 0001

Report No.: 31791540 004

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

Products:
Products and Facilities: see attachments

Replaces Approval, Registration No.: HD 60112650 0001

Expiry Date: 2023-11-07

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: 2018-12-03

Date: 2018-12-03

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
Notified Body
TÜVRheinland®
III
S. Liu

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60133912 0001
Report No.: 31791540 004

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

Defibtech, L.L.C.
4 Progress Avenue
Seymour, CT 06483 USA

Defibtech, L.L.C.
14 Commercial Street
Branford, CT 06405 USA

Date: 2018-12-03

Notified Body
S. Liu

TÜVRheinland®

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60133912 0001
Report No.: 31791540 004

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

Products:
- Semi-automatic External Defibrillators
- Fully-automatic External Defribillators
- Battery Packs (for Semi-automatic and Fully-automatic External Defibrillators)
- Defibrillation Electrodes (for Semi-automatic and Fully-automatic External Defibrillators)
- ECG Monitoring Adapters
- Pad Adapters for Defibrillation Electrodes
- Automated Chest Compressors
- Battery Packs (for Automated Chest Compressor)
- Patient Interface Pad (for Automated Chest Compressor)

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

S. Liu

Date: 2018-12-03