

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

**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 - 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



**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 Defibrillators
- 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)

**Date:** 2018-12-03

