

# EC Certificate

**Full Quality Assurance System**

**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 2218527-1

Manufacturer: Defibtech, LLC  
741 Boston Post Road, Suite 201  
Guilford CT 06437  
USA

Products: Semi-Automatic External Defibrillators  
Automatic External Defibrillators  
Battery Packs  
Battery Chargers  
Defibrillation Electrodes  
ECG Monitoring Adapters  
Automated Chest Compressors  
Automated Chest Compressor Frames  
Automated Chest Compressor Backboards  
Stabilization Straps  
Wrist Straps  
Patient Interface Pads

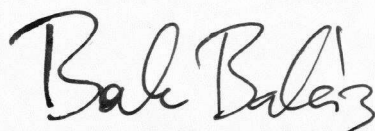
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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.

Report No.: 234164499-10

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25



Balazs Bozsik  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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

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USA

The scope of certification includes the following manufacturing sites:


No.	Location	Scope
/01	Defibtech, LLC 741 Boston Post Road, Suite 201 Guilford CT 06437 USA	Activities related to design, development and manufacturing
/02	Defibtech, L.L.C. 4 Progress Avenue Seymour CT 06483 USA	Activities related to manufacturing
/03	Defibtech, L.L.C. 14 Commercial St Branford CT 06405 USA	Activities related to manufacturing

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