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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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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