

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture, Distribution and
Service of Medical Devices
(see attachment for products and sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-04-20
Certificate Registration No.: SX 60144228 0001
An audit was performed. Report No.: 31990606 001
This Certificate is valid until: 2022-11-07

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-04-20



Balazs Bozsik

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60144228 0001
Report No.: 31990606 001

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

Scope:

Products:
Semi-automatic and Fully-automatic External Defibrillators
and Accessories and External Cardiac Compressors and
Accessories

Sites included:
Defibtech, L.L.C.
741 Boston Post Road, Suite 201, Guilford, CT 06437 USA
Scope: Activities related to Design and Development,
Distribution, and Administration

Defibtech, L.L.C.
14 Commercial Street, Branford, CT 06405 USA
Scope: Activities related to Manufacture, Distribution
and Service

Defibtech, L.L.C.
4 Progress Avenue, Seymour, CT 06483 USA
Scope: Activities related to quality control of
purchased parts

Certification Body



Balazs Bozsik
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Date: 2020-04-20