

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2218527-1

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

Scope: Design and Development, Manufacturing, Distribution and Service of Semi-automatic and Fully-automatic External Defibrillators and Accessories, and External Cardiac Compressors and Accessories.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 234180332-11
Effective date: 2022-08-15
Expiry date: 2024-08-31
Issue date: 2022-08-15



Aihe Huang

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



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No.	Facility	Scope
/01	Defibtech, L.L.C. 741 Boston Post Road, Suite 201 Guilford CT 06437 USA	Activities related to Design and Development, and administration.
/02	Defibtech, L.L.C. 14 Commercial St Branford CT 06405 USA	Activities related to Manufacture, Distribution and Service.

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