

APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60024624 0001

Report No.: 30892269 001

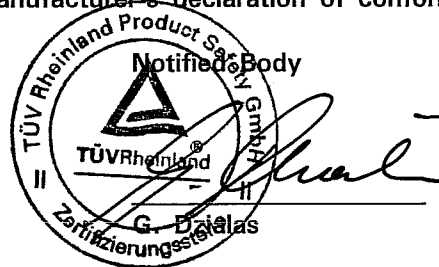
Manufacturer: Defibtech, LLC
741 Boston Post Road, Suite 201
Guilford CT 06437
USA

Scope: Design/Development and Manufacture of
Semi-automatic External Defibrillators
Products and Facilities: see attachment
Replaces Approval, Registration No. : HD 60015243 0001

Date of Expiry: 23.12.2013

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 10.04.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with.

CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HD 60024624 0001
Report No.: 30892269 001

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

Scope: Facilities:

Defibtech, LLC
Manufacturing Site
4 Progress Avenue Seymour, CT 06483 USA

Products:

- Semi-automatic External Defibrillators

Cologne, 10.04.2009

