



TÜVRheinland®

Genau. Richtig.

**Product Safety and Quality
Certification Department**

TÜV Rheinland Product Safety GmbH D-51105 Cologne

Mr. Horton
Defibtech, LLC
741 Boston Post Road, Suite 201
GUILFORD 06437
USA

Tel. +49 180 3 112 112
Fax +49 180 3 000 169
Mail safety@de.tuv.com

Customer Service Center for
Product Safety and Quality
Tel. +49(0)221-806-1400
Mail service@de.tuv.com

Cologne, September 25, 2009

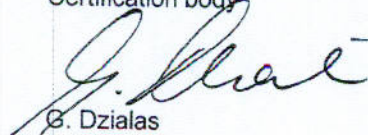
Application for : Vollst. QMS, Anhang II MDD
Certificate No. : HD 60026981 SHEET 0001
Techn. appliance : Only for QM-System audit
Test requirements : Richtlinie 93/42/EWG

Dear Mr. Horton,

Enclosed please find the
new certificate No. HD 60026981 0001
replacing the previous certificate.

Kind regards

Certification body



G. Dzialas

Test sample: no, documentation available

TÜV Rheinland
Product Safety GmbH

TÜV Rheinland Group

Am Grauen Stein
51105 Cologne

Tel. +49 180 3 112112
Fax +49 180 3 000169
Mail safety@tuv.com
Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Michael Jungnitsch

Dipl.-Wirtsch.-Ing.
Hans-Hermann Ueffing

Cologne HRB 25960
UST-ID Nr.: DE 811835490

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

Registration No.: HD 60026981 0001

Report No.: 30892269 003

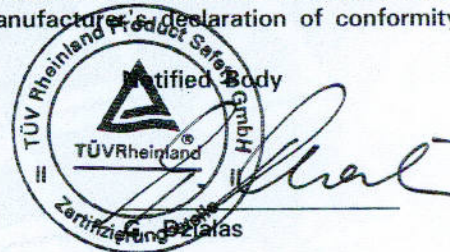
Manufacturer: Defibtech, LLC
741 Boston Post Road, Suite 201
Guilford CT 06437
USA

Scope: Design/Development and Manufacture of
External Defibrillators
Products and Facilities: see attachment
Replaces Approval, Registraion No. : HD 60024624 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, 23.09.2009



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 60026981 0001
Report No.: 30892269 003

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
- Fully-automatic External Defibrillators

Cologne, 23.09.2009

