Product Safety and Quality
Certification Department

TÜVRheinland®
Genau. Richtig.

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

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51105 Cologne

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Board of Management

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Cologne HRB 25960
UST-ID Nr.: DE 811835490

TÜVRheinland®

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.

TÜV Rheinland Product Safety GmbH Notified Body TÜVRheinland Zertifizierstelle Dziatas

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

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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

Certification Body

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

G. Dzialas

Cologne, 23.09.2009