Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Mr. Ed Horton
Defibtech, L.L.C.
741 Boston Post Road, Suite 201
GUILFORD 06437
USA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date September 20, 2014

Application for : **Vollst. QMS, Anhang II MDD**
Certificate No. : HD 60096464 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Mr. Horton,

Enclosed please find the
new certificate No. HD 60096464 0001
replacing the previous certificate.

Kind regards

Certification body

Jürgen Welte

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

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TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60096464 0001

Report No.: 31291366 004

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

Products:
External Defibrillators and Automated Chest Compressors

Products and Facilities: see attachment

Replaces Approval, Registration No. : HD 60091000 0001

Expiry Date: 2018-11-07

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2014-09-12

Date: 2014-09-12

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

Jürgen Welte

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60096464 0001
Report No.: 31291366 004

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

Facilities:
Defibtech, L.L.C.
4 Progress Avenue
Seymour, CT 06483 USA
Scope: Activities related to Manufacturing

Products:
- Semi-automatic External Defibrillators
- Fully-automatic External Defribillators
- Automated Chest Compressors

Notified Body

Date: 2014-09-12

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Jürgen Welte

Překlad z jazyka anglického:

Business Stream Products
Certifikační oddělení

TÜV Rheinland®
LGA
Přesně správné.

TÜV Rheinland LGA Products GmbH - 90431 Nürnberg

Kontakt:

Tel: + 49 911 656-5225
e-mail: service@de.tuv.com
Datum: 20. září 2014

Pan Ed Horton
Defibtech, L.L.C
741 Boston Post Road, Suite 201
USA

Žádost pro:	**Vollst. QMS, příloha II MDD**
Číslo osvědčení:	HD 60096464 List 0001
Zařízení:	Pouze pro audit systému řízení jakosti
Požadavek na test:	Směrnice 93/42/EWG

Vážený pane Hortone,

přikládám nové osvědčení číslo HD 60096464 0001,
které nahrazuje dřívější osvědčení.

S pozdravem

Certifikační orgán

- nečitelný podpis -

Jürgen Welte
Zkušební vzorek: žádná dokumentace k dispozici

TÜV Rheinland
LGS Products GmbH

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Jörg Mähler, mluvčí

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