EC Certificate

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

Registration No.: HD 60133912 0001

Report No.: 31791540 004

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

Products:
Products and Facilities: see attachments

Replaces Approval, Registration No.: HD 60112650 0001

Expiry Date: 2023-11-07

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.

Effective Date: 2018-12-03

Date: 2018-12-03

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
S. Liu
Zertifizierungsstelle

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.

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2022.08.18 16:56:09 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60133912 0001
Report No.: 31791540 004

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

Defibtech, L.L.C.
4 Progress Avenue
Seymour, CT 06483 USA

Defibtech, L.L.C.
14 Commercial Street
Branford, CT 06405 USA

Date: 2018-12-03

Notified Body
S. Liu

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Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60133912 0001
Report No.: 31791540 004

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

Products:
- Semi-automatic External Defibrillators
- Fully-automatic External Defribillators
- Battery Packs (for Semi-automatic and Fully-automatic External Defibrillators)
- Defibrillation Electrodes (for Semi-automatic and Fully-automatic External Defibrillators)
- ECG Monitoring Adapters
- Pad Adapters for Defibrillation Electrodes
- Automated Chest Compressors
- Battery Packs (for Automated Chest Compressor)
- Patient Interface Pad (for Automated Chest Compressor)

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

S. Liu

Date: 2018-12-03

Lifeline ARM

Automated chest compression device for professionals

Precise operation of the Lifeline ARM helps to ensure high-quality and continuous cardiopulmonary resuscitation (CPR) associated with better survival for victims of sudden cardiac arrest (SCA)[1].

With an innovative and elegant design, the Lifeline ARM is an automated solution for providing victims of sudden cardiac arrest high-quality and continuous CPR that is associated with better survival outcomes.[2] Easy to deploy and use, the device delivers compressions, with complete chest recoil, at the depth and rate recommended by the AHA/ERC cardiopulmonary resuscitation guidelines. Using a proprietary algorithm that compensates for variability in patient chest resistances, the Lifeline ARM delivers precise compressions, an important factor for effective CPR.[3]

defibtech

NIHON KOHDEN

Lifeline ARM

Removable compression module

The removable compression module is unique to the Lifeline ARM. Its modularity facilitates easy deployment and makes it much more convenient to use and service. The module houses a software controlled motor and the compression piston. In conjunction with the frame and backboard, the compression module delivers chest compressions at a consistent depth and rate without undue frame deflection or distortion, both of which impact CPR efficacy.[1]

- The module provides high quality CPR (recommended depth and rate) with full chest recoil without interruptions according to AHA/ ERC Guidelines
- A proprietary algorithm ensures consistent depth and rate of the compressions across a wide range of patient chest resistances
- A custom designed brushless DC motor drives the compression piston delivering smooth and consistent operation

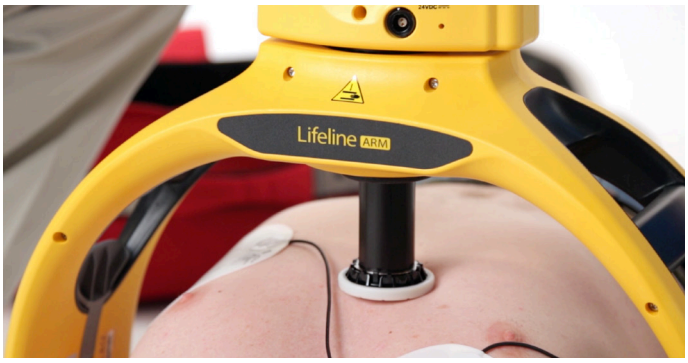
Maximum patient accessibility

Self-centering and self-locking latches on the frame make it easy to match up with, and securely snap into, the backboard.

- Two sets of wide release levers, located on each side of the frame, provide multiple frame release options
- Purposeful redundancy of release levers enables easy detachment of both sides of the frame, or one side at a time
- Integrated patient lift handles
- Simultaneous defibrillation is possible

Increased structural integrity

For superior performance during compressions, a rigid frame and backboard enable operation without unwanted flex.



- Single-piece design of the frame enhances usability during deployment and use
- Stiff structure provides consistent compression depth, an important element for patient survival[1]
- Accommodates a broad range of adult patient sizes (weight is not a factor)
- Provides high quality CPR delivery during transport
- Well-balanced and lightweight

Intuitive interface with real-time CPR protocol selection

The Lifeline ARM's simplified control panel requires just two steps to initiate mechanical CPR.

1. Adjust the compression piston's height relative to the patient's chest using the Up/Down buttons,
2. Select from two rescue protocols by pressing the corresponding soft key: Chest compressions only (no breaths), or chest compressions with rescue breaths.

With real-time CPR protocol selection, you can switch between the two protocols during the rescue

- The compressions with breaths protocol has timed pauses programmed into the compression cycle to allow for rescue breaths
- At any time, compressions may be stopped (paused), or resumed

Unmatched operating times

With the Lifeline ARM's longer battery life, it is especially suited for extended periods of uninterrupted CPR accommodating long transports to, or lengthy treatments in, a hospital.

By design, the Lifeline ARM may be operated using the recharge-able battery pack or the external AC power adapter, which even during use is capable of recharging the battery pack.

- Fastest in-unit recharge time
- Higher number of charge/discharge cycles
- Rapid battery pack swapping
- Battery pack can be inserted in multiple orientations

Highly visible and portable

Time is of the essence in a rescue, and equipment needs to be easy to carry, deploy, and pack up. The lightweight Lifeline ARM comes with a canvas carrying case designed for backpack portability.

Built to withstand demanding environments

The structural design of the frame and backboard, and the housing of the compression module, combine to contribute to its extreme durability, strength, and impact resistance, making it one tough unit. Designed to be reliable and rugged, the Lifeline ARM is protected against ingress and fluid spray, and it meets military standards for vibration.

Easy to maintain and field serviceable

The removable compression module makes it much more convenient to use, maintain, perform field updates, and ship-in for service.

- A USB port on the module supports data recovery of event data for post event review
- Software updates may be performed in the field making the Lifeline ARM adaptable to future resuscitation requirements
- Scheduled preventive maintenance is only needed every 18 months

[1] Wik L, et al: Quality of Cardiopulmonary Resuscitation during Out-of-Hospital Cardiac Arrest. JAMA. 2005;293(3):299-304. doi:10.1001/jama.293.3.299.
[2] Kleinman ME, et al: 2015 American Heart Association guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Part 5: Adult Basic Life Support & CPR Quality. Circulation (2015); 132:S414-S435.

Specifications

Lifeline ARM (RMU-1000)

Compressions

Compression modes	Continuous Compressions; Compressions with Breathing (30:2, 30 compressions with 3-second pause for ventilation) factory default; future protocols via field updates
Compression depth	2.1 inches ±0.1 inches (5.3 cm ±0.3 cm) from start position (nominal patient)
Compression frequency	101 ±1 compressions per minute
Compression duty cycle	50% ±5%

Dimensions and weight

Size (assembled)	59.7 x 52.7 x 22.9 cm
Size (in carrying case)	50.8 x 50.8 x 25.4 cm
Weight (with battery pack)	7.1 kg
Adult patient ranges	Adult patients that fit into the ACC: Chest width – 45.7 cm max Chest height – 16.5 to 30 cm Use of the Lifeline ARM is not restricted by patient weight

AC Power Adapter

Model number	RPM-1000
Rated output	24.0V ±5% at 4.2A
Input voltage	85 - 264VAC (100 - 240VAC nominal)
Input frequency	47 - 63Hz
Input current	<2.3A rms
Operating temperature	0 to 40°C full load
Storage temperature	-40 to 85°C
Electromagnetic compatibility (emissions and immunity)	IEC 60601-1-2

Environmental

Operating / maintenance temperature	0 to 40°C
Stand-by / storage / transport temperature	-20 to 70°C
Humidity	5% to 95% (non-condensing)
Vibration	MIL-STD-810G 514.6 Category 20 (Ground)
Sealing / water resistance	IEC 60529 class IP43 (battery pack installed)
Electromagnetic compatibility (emissions and immunity)	IEC 60601-1-2:2007/AC: 2010
Design standards	Meets applicable requirements of: • IEC 60601-1 • UL 60601-1 • CAN/CSA C22.2 60601-1 • IEC 60601-1-2
Device classification	Internally powered Class II (with external power source)

Battery Pack

Model number	RBP-1000
Battery type	18.5V, 5300 mAh, Lithium-ion. Rechargeable, recyclable.
Operation time	1 hour (normal patient)*
Battery pack charging time	Less than 3 hours in ACC*; less than 2 hours in external battery pack charging station*
Battery pack useful life	Recommended to replace battery pack every 3 years or if battery pack indicator displays a replace battery pack condition (~300 charge/discharge cycles)
Battery pack operating time	1 hour
Charging temperature	0 to 40°C ambient
Storage temperature	0 to 40°C; -20 to 60°C short-term <1 month
Sealing/water resistance	IEC 60529 class IP44

***typical, with new battery at 25° C**

NIHON KOHDEN EUROPE GmbH
Raiffeisenstr. 10, 61191 Rosbach, Germany
Phone: +49 6003 827 0, Fax: +49 6003 827 599
Internet: www.nihonkohden.com, E-mail: info@nke.de

Defibtech, LLC
Guilford, CT 06437, USA
Phone: +1-203-453-4507
Internet: www.defibtech.com

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defibtech

E/DS-RMU1000-DE01

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture, Distribution and Service of Medical Devices
(see attachment for products and sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-04-20
Certificate Registration No.:	SX 60144228 0001
An audit was performed. Report No.:	31990606 001
This Certificate is valid until:	2022-11-07

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Date 2020-04-20

Balazs Bozsik

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60144228 0001
Report No.: 31990606 001

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

Scope:

Products:
Semi-automatic and Fully-automatic External Defibrillators and Accessories and External Cardiac Compressors and Accessories

Sites included:
Defibtech, L.L.C.
741 Boston Post Road, Suite 201, Guilford, CT 06437 USA
Scope: Activities related to Design and Development, Distribution, and Administration

Defibtech, L.L.C.
14 Commercial Street, Branford, CT 06405 USA
Scope: Activities related to Manufacture, Distribution and Service

Defibtech, L.L.C.
4 Progress Avenue, Seymour, CT 06483 USA
Scope: Activities related to quality control of purchased parts

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-20

Balazs Bozsik

DECLARATION OF CONFORMITY

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

Declares that the CE marked product:

Product:	Automated Chest Compressor System (accessories and components sold as part of system and also sold individually)
Family Models:	**RMU-1000**
Product:	Battery Charger (and components)
Family Models:	**RBC-1000**

complies with all applicable provisions of the Council Directive 93/42/EEC (Medical Device Directive). The technical file required by this Directive is maintained at the Manufacturer site listed above.

Rule 9, Section III (Classification), Annex IX (Classification Criteria) of the Council Directive 93/42/EEC (concerning Medical Devices) was used to classify the products listed above as Class IIb medical devices.

Technical File Reference Document TF-00014 lists all standards that apply.

Valid from 12/03/2018 to 11/07/2023

Notified Body: **0197 – TUV Rheinland LGA Products GmbH**
Tillystraße 2, 90431 Nürnberg Germany

Registration Number: **HD 60133912 0001**

European Authorized Representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Ed Horton

December 3, 2018

Ed Horton
Vice President, Quality and Regulatory Affairs
Defibtech, LLC

Date

ELECTRONIC DISTRIBUTION

RAC-G1710EN-BF