TÜVRheinland®

EC Certificate

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

Registration No.: HD 60112157 0001

Report No.: 21196116 007

Manufacturer:
Löwenstein Medical Technology
GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

Products:
Medical devices for oxygen-, emergency- and sleep medicine, ventilation, diagnosis, and defibrillation
(see attachment for products and sites included)

Replaces EC-Certificate, Registration No.: HD 60085534 0001

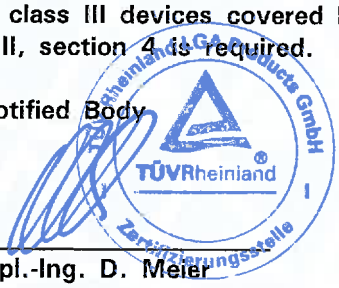
Expiry Date: 2018-05-21

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: 2016-07-27

Date: 2016-07-27

Notified Body



Dipl.-Ing. D. Meier

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.

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Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60112157 0001
Report No.: 21196116 007

Manufacturer: Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

Products included:

Sleep Diagnostics
- Sleep Apnea Diagnostic Systems
- Polygraphy
- Polysomnography
- Sleep Diagnostic Software

Sleep Therapy
- Sleep Apnea Therapy Systems
- Heated Humidifiers
- Breathing Tubes
- Oxygen Valves
- Bacteria Filters
- Sleep Therapy Software

Notified Body

Date: 2016-07-27

Dipl.-Ing. D. Meier

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Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60112157 0001
Report No.: 21196116 007

Manufacturer: Löwenstein Medical Technology GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

Products included:
Ventilation
- Ventilation Systems
- Heated Humidifiers
- Oxygen Valves
- SpO2 Module
- Ventilation Software

Patient Interface
- Breathing Masks
- Exhalation Systems

Sites included:
Löwenstein Medical Technology GmbH + Co. KG
Siebenstücken 14
24558 Henstedt-Ulzburg, Germany

MCC GmbH & Co. KG
Südendstraße 42
76135 Karlsruhe, Germany

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. D. Meier

Date: 2016-07-27

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Weinmann Geräte für Medizin GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

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

Design and development, production, distribution and servicing of medical devices
(see attachment for products and sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Certificate Registration No.: SX 60085540 0001

An audit was performed. Report No.: 21196116 001

This Certificate is valid until: 21.05.2018

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 22.05.2013

Dipl.-Ing. D. Meier

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60085540 0001
Report No.: 21196116 001

Organization:
Weinmann Geräte für
Medizin GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg
Deutschland

Scope:

Medical Devices for Oxygen Medicine, Emergency Medicine, Sleep Medicine, Home Mechanical Ventilation, Diagnosis as well as Defibrillators

Additional production and servicing sites included:

Weinmann Geräte für Medizin GmbH + Co. KG
Siebenstücken 14, 24558 Henstedt-Ulzburg, Germany

Additional design and development site included:

MCC GmbH & Co. KG
Südendstraße 42, 76135 Karlsruhe, Germany

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Date: 2013-05-22

Certification Body

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Dipl.-Ing. D. Meier