

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

Registration No.: HD 60131384 0001

Report No.: 21196116 018

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

Products: Medical devices for sleep medicine, ventilation,
patient interface and diagnosis
(see attachment for products and sites included)

Replaces EC-Certificate, Registration No.: HD 60129205 0001


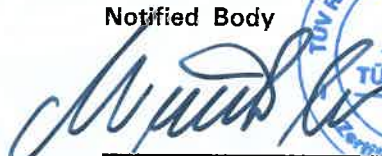
Expiry Date: 2023-05-21

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: 2018-07-26

Date: 2018-07-26

Notified Body



Dipl.-Ing. I. Munkler

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

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

Products included:

Sleep Diagnostics:

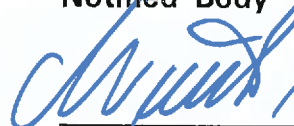
- Sleep Apnea Diagnostic Systems
- Polygraphy
- Polysomnography
- Sleep Diagnostic Software

Sleep Therapy:

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

Date: 2018-07-26

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Dipl.-Ing. I. Munkler



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Certificate**

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Products included:

Ventilation:

- Ventilation Systems
- Heated Humidifiers
- Oxygen Valves
- SpO2 Module
- Ventilation Software

Patient Interface:


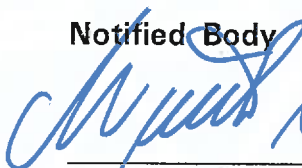
- Breathing Masks
- Exhalation Systems

Site included:

Löwenstein Medical Technology GmbH + Co. KG
Site Karlsruhe
Südenstraße 42
76135 Karlsruhe, Germany

Date: 2018-07-26

Notified Body



Dipl.-Ing. I. Munkler