

**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


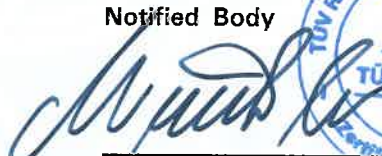
**Expiry Date:** 2023-05-21

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**

**Registration No.:** HD 60131384 0001  
**Report No.:** 21196116 018

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

**Products included:**

**Sleep Diagnostics:**

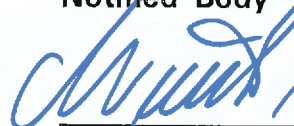
- Sleep Apnea Diagnostic Systems
- Polygraphy
- Polysomnography
- Sleep Diagnostic Software

**Sleep Therapy:**

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

**Date:** 2018-07-26

**Notified Body**



**Dipl.-Ing. I. Munkler**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60131384 0001  
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**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:**


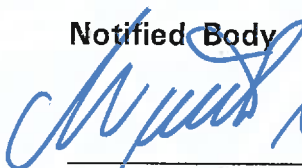
- Breathing Masks
- Exhalation Systems

**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**