

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

**Registration No.:** HD 60128634 0001

**Report No.:** 21247034 010

**Manufacturer:** WILAmed GmbH  
Aurachhöhe 5-7  
91126 Kammerstein  
Deutschland

**Products:** Medical devices for respiration therapy  
(see attachment for products included)  
Replaces Certificate, Registration No.: HD 60102409 0001

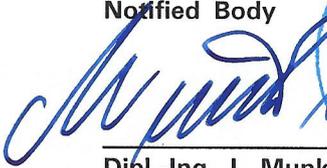
**Expiry Date:** 2023-05-28

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:** 2018-05-29

**Date:** 2018-05-02

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**

**Attachment to  
Certificate**

**Registration No.:** HD 60128634 0001  
**Report No.:** 21247034 016

**Manufacturer:** WILAméd GmbH  
Aurachhöhe 5-7  
91126 Kammerstein  
Deutschland

Products included:

- WILAtube, Tube systems heated and unheated
- WILAsilent, Valves non-rebreathing
- WILAflo Elite, Neonatal Ventilator
- Humidification chamber
- Oxi.Plus, Breathing and sleep apnea masks
- AIRcon, Humidifiers, heated
- AIRcon Gen2, Humidifiers, heated
- AIRniva, Humidifiers, heated
- prisma VENT AQUA, Humidifiers, heated
- INTENSA Go, Ventilator
- INTENSA, Ventilator

**Date:** 2019-04-18

**Notified Body**

**Roland Gruber**

