

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: WILAméd 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

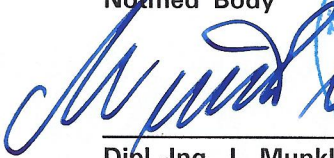

Expiry Date: 2023-05-28

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

Doc. 1/1, Rev. 1

**Attachment to
Certificate**

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

Manufacturer: WILAmed GmbH
Aurachhöhe 5-7
91126 Kammerstein
Deutschland

Products included:

- WILAtube, Tube systems heated and unheated
- WILAsilent, Valves non-rebreathing
- WILAflow 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

