TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

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Doc. 1/1, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

Notified Body

Date: 2019-04-18

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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