

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

Registration No.: HD 60147519 0001

Report No.: 21197407 023

Manufacturer: HUM Gesellschaft für
Homecare und Medizintechnik mbH
Zum Pier 79
44536 Lünen
Deutschland

Products: Medical devices for ventilation, respiratory therapy,
emergency medicine and patient monitoring
(see attachment for products included)

Replaces Certificate, Registration No.: HD 60129649 0001



Expiry Date: 2024-05-26

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: 2020-04-15

Date: 2020-04-15

Notified Body



TÜVRheinland®
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.

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

**Attachment to
Certificate**

Registration No.: HD 60147519 0001
Report No.: 21197407 023


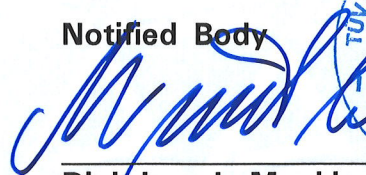
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Products included:

- Sterile water for irrigation and inhalation
- Pulse oximeters
- Breathing tubing and breathing tubing systems
- Oxygen cannulas, -masks and -tubings
- Humidifiers
- High pressure regulators
- Flowmeters
- Suction regulators
- Devices for respiratory home care therapy
- Resuscitator bags
- Resuscitator masks
- Airway tubes
- PEEP-valves
- CPR Pocket masks
- Tubing extensions

Date: 2020-04-15

Notified Body



Dipl.-Ing. I. Munkler