TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60149001 0001

Report No.: 21197407 027

Manufacturer:

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

Products:

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

Replaces Approval, Registration No.: DD 60129645 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-04-27

Date: 2020-04-27

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.: DD 60149001 0001
Report No.: 21197407 029

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

Products included:

- Air filters, gas filters and bacterial filters
- Oxygen cannulas, -masks and -tubings
- Breathing tubing and breathing tubing systems
- Nebulizer masks
- Suction catheters
- Heat and moisture exchangers
- Airway tubes
- Suction hoses

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. U. Frenkert

Date: 2021-05-20