



Certificate

No. Q5 071635 0038 Rev. 02

Holder of Certificate: **Vyaire Medical GmbH**
Leibnizstrasse 7
97204 Höchberg
GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Active Medical Devices for the following Areas: Lung Function Diagnostics, Sleep Diagnostics, Electrocardiographs- Multichannel with Computer for ECG Interpretation, Spirometers, Calibration Syringes, Alveolar Gas Analysers, Airway Resistance Monitors including related respiratory PC Analysis Software, Respiratory PC Analysis Software, Pulse Wave Monitors, Aerosol Provocation Systems, Mechanical Peak Flow Meters, Mouthpieces and Bacteria Filters. Servicing, Maintenance, Repair and Distribution of Lung Function Diagnostic Devices, Sleep Diagnostic Devices, Ventilators and Gas Therapy Monitors. Servicing, Maintenance and Distribution of CPAP Devices. Distribution of ECG Patient Cables, Breathing Masks, Blood Pressure Cuffs and Nasal Prongs**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 071635 0038 Rev. 02

Report No.: 713202381

Valid from: 2021-05-01
Valid until: 2024-04-30

Date, 2021-04-28



Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Vyair Medical GmbH
Leibnizstrasse 7, 97204 Höchberg, GERMANY

Design and Development, of Active Medical Devices for the following areas: Lung Function Diagnostics, Sleep Diagnostics, Electrocardiographs-Multichannel with Computer for ECG Interpretation, Spirometers, Calibration Syringes, Alveolar Gas Analyzers, Airway Resistance Monitors including related respiratory PC Analysis Software, Respiratory PC Analysis Software, Pulse Wave Monitors, Aerosol Provocation Systems, Mechanical Peak Flow Meters, Mouthpieces and Bacteria Filters Servicing, Maintenance, Repair of Lung Function Diagnostic Devices, Sleep Diagnostic Devices, Ventilators and Gas Therapy Monitors
Servicing, Maintenance and Distribution of CPAP Devices

Vyair Medical GmbH
Max-Planck-Strasse 10, 97204 Höchberg, GERMANY

Production and Distribution of Active Medical Devices for the following areas: Lung Function Diagnostics, Sleep Diagnostics, Electrocardiographs-Multichannel with Computer for ECG Interpretation, Spirometers, Calibration Syringes, Alveolar Gas Analyzers, Airway Resistance Monitors including related respiratory PC Analysis Software, Respiratory PC Analysis Software, Pulse Wave Monitors, Aerosol Provocation Systems, Mechanical Peak Flow Meters, Mouthpieces and Bacteria Filters Distribution of Lung Function Diagnostic Devices, Sleep Diagnostic Devices, Ventilators and Gas Therapy Monitors
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