



# Certificate

No. Q5 010815 0037 Rev. 01

**Holder of Certificate:** Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place  
East Tamaki, Auckland 2013  
NEW ZEALAND

**Facility(ies):** Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place, East Tamaki,  
Auckland 2013, NEW ZEALAND

See scope of certificate

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Respiratory Gas Delivery Systems, Heated Humidifiers, Infant Radiant Warmers, Continuous Positive Airway Pressure Units, CPAP Data Transmission Equipment, Gas Powered Pulmonary Resuscitators, Nasal and/or Oral Interfaces for Delivery of Respiratory Gases, Patient Monitoring Software for Use with Fisher & Paykel Healthcare Medical Devices, Insufflation Gas Conditioning Systems

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

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 010815 0037 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 010815 0037 Rev. 01)



Product Service

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Report No.: JA1669262  
Valid from: 2021-11-14  
Valid until: 2024-11-13

Date, 2021-11-11

Christoph Dicks  
Head of Certification/Notified Body