



Product Service

CERTIFICATE

No. Q1N 10 04 10815 020

Holder of Certificate: Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place
East Tamaki, Auckland
NEW ZEALAND

Facility(ies): Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki, Auckland,
NEW ZEALAND

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, Gas Powered Pulmonary Resuscitators, Nasal and/or Oral Interfaces for Delivery of Respiratory Gases, Patient Monitoring Software for Use with Obstructive Sleep Apnea Devices, Insufflation Gas Conditioning Systems

Applied Standard(s): EN ISO13485: 2003 / AC: 2007
ISO13485: 2003
Medical Devices
- Quality Management Systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: OAQ73526984A

Valid until: 2013-07-31

Hans-Heiner Junker



Date, 2010-08-01

Page 1 of 1

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany



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Zentralstelle der Länder
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bei Arzneimitteln
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