



Product Service

# EC - CERTIFICATE

## Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 09 11 10815 018

**Manufacturer:** Fisher & Paykel Healthcare Limited  
15 Maurice Paykel Place  
East Tamaki, Auckland  
NEW ZEALAND

**EC-Representative:** Fisher & Paykel Healthcare Ltd  
Unit 16, Cordwallis Park, Clivement Rd.  
Maidenhead  
SL6 7BU  
UNITED KINGDOM

**Product Category(ies):** Oxygen Therapy Delivery Systems (includ. Ster. Circuits), Stationary Infant and Adult Radiant Warmers, Heated Humidifiers (incl. Humidification for Laparoscopy) Phototherapy Light Units Continuous Positive Airway Pressure Units, Gas-powered Pulmonary Resuscitators, Electrical Peripheral Nerve Block Monitoring Stimulators

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

**Report No.:** OAQ73525604

**Valid until:** 2015-03-19

**Date,** 2010-03-20

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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