ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 12 10815 026

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

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

Product Category(ies):
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

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 devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **OAQ235015552A**

Valid from: **2015-03-20**
Valid until: **2020-03-19**

Date, **2015-02-18**

Hans-Heiner Junker

638177

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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No. G1 14 12 10815 026

Facility(ies):

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

Fisher & Paykel Healthcare S.A. de C.V.
Ave. Todos Los Santos 12831, Parque Industrial
Pacifico, 22643 Tijuana, Baja California, MEXICO

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