ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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 16 02 10815 027

Manufacturer:

Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place
East Tamaki, Auckland 2013
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.: JAQ235023472

Valid from: 2016-04-08
Valid until: 2020-03-19

Date, 2016-04-08

Stefan Preiß

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

Digitally signed by Grabar Alexandru
Date: 2019.03.05 14:21:31 EET
Reason: MoldSign Signature
Location: Moldova

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Facility(ies):

Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place, East Tamaki, Auckland 2013, 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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