A4 / 07.17







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)

zig.de

No. G1 010815 0038 Rev. 01

Manufacturer:

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

Product Category(ies): Respiratory Gas Delivery Systems, Heated Humidifiers, 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 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.:

JAQ235040717

Valid from: Valid until:

2019-12-12 2024-05-26

Date.

2019-12-12

Christoph Dicks Head of Certification/Notified Body

Page 1 of 2 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123







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 010815 0038 Rev. 01

Facility(ies):

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

-/-

Zertifiziervertrag

Grundlage für die Zertifikatserteilung ist die Prüfund Zertifizierordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuevsued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

Gültigkeit der zitierten normativen
 Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:

 Voraussetzungen f
ür vorschriftsm
ä
ßige Fertigung werden eingehalten.

• Validity of the quoted test standard(s)

certification mark and for QM certificates:

• Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Requirements for the validity of the certificate

In addition, for certificates with the right to use a

Conditions for an adequate manufacturing are

Regular surveillance of the facility is performed

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuvsud.com/ps_regulations) and thus becomes partner

in the TÜV SÜD Product Service Certification System.

认证合约

认证基于 TÜV SÜD 产品服务《测试及认证准则》。 获得证书即表明证书持有者接受当前版本的《测试及 认证准则》(见 www.tuv-sud.com/ps_regulations) 并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求:

in principle:

maintained

• 认证所依据标准的有效性

此外,对于授权可使用认证标志的证书和质量管理 体系证书:

- 保持充分的生产条件
- 生产场地通过定期的监督

認証契約

認証は TÜV SÜD Product Service の試験認証規約に 基づく。認証書保持者は認証書を受領することによ り最新の試験認証規約(www.tuv-

sud.com/ps_regulations)に同意したものとする。

その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項

• 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品 質マネジメント認証書は:

- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

Contrato de certificação

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD. Requisitos para a validade do certificado (em princípio):

• Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:

- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.