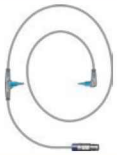
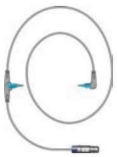
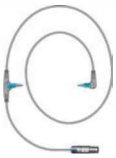
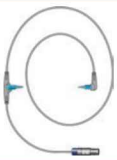
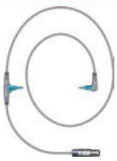
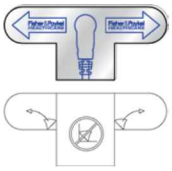
Humidifier and accessories

Product Code	Description	Quantity	
MR850XXX	MR850™ respiratory heated humidifier (XXX indicates regional plug variation)	1 each	
900MR805	Heater-wire adapter for dual-heated breathing circuits	1 each	
900MR806	Heater-wire adapter for inspiratory heated breathing circuits	1 each	
900MR863	Temperature/Flow probe adapter for use with circuits 0.7 m (28″) long	1 each	
900MR868	Temperature/Flow probe adapter for use with circuits 1.1 m (44″) long	1 each	
900MR860	Temperature/Flow probe adapter for use with circuits 1.3 m (52″) long	1 each	
900MR869	Temperature/Flow probe adapter for use with circuits 1.5 m (60″) long	1 each	
900MR861	Temperature/Flow probe adapter for use with circuits 1.8 m (72″) long	1 each	
900MR870	MR850 calibration reference probe	1 each	
900MR208	Reflective shield for temperature probe	20 pack	

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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 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: **2019-12-12**
Valid until: **2024-05-26**

Date, **2019-12-12**

Christoph Dicks
Head of Certification/Notified Body

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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 010815 0038 Rev. 01

Facility(ies):

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

-/-

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Zertifiziervertrag
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.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 für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

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.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

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：
- 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.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010815 0037 Rev. 01

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

Facility(ies):
Fisher & Paykel Healthcare Ltd.
15 Maurice Paykel Place, East Tamaki,
Auckland 2013, NEW ZEALAND

See scope of certificate

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,
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

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 010815 0037 Rev. 01

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010815 0037 Rev. 01

Report No.:	**JA1669262**
Valid from:	**2021-11-14**
Valid until:	**2024-11-13**

Date, **2021-11-11**

Christoph Dicks
Head of Certification/Notified Body

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 010815 0039 Rev. 02

Manufacturer:

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

SRN Manufacturer: **NZ-MF-000002556**

Authorized Representative:

Fisher & Paykel Healthcare SAS
10 Avenue du Québec, Bâtiment F5, BP 512, Villebon-Sur-Yvette, 91946 Courtaboeuf CEDEX, FRANCE

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 010815 0039 Rev. 02

Report No.: JA63392435

Preceding Certificate No.: G10 010815 0039 Rev. 01

Valid from: 2023-04-17
Valid until: 2026-12-05

Date of Initial Issuance: 2021-12-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-04-17

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BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 010815 0039 Rev. 02

Classification:	Class IIa
Device Group:	R060201 - ACTIVE VENTILATION HUMIDIFICATION SYSTEMS,
Intended Purpose:	-/-
Classification:	Class IIb
Device Group:	R060201 - ACTIVE VENTILATION HUMIDIFICATION SYSTEMS,
Intended Purpose:	To provide heat and humidity to respiratory gases delivered to patients
Classification:	Class IIa
Device Group:	R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose:	-/-
Classification:	Class IIa
Device Group:	R030101 - VENTILATION MASKS
Intended Purpose:	-/-
Classification:	Class IIa
Device Group:	R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS
Intended Purpose:	-/-
Classification:	Class IIa
Device Group:	R060280 - HUMIDIFICATION SYSTEMS - ACCESSORIES
Intended Purpose:	-/-
Classification:	Class IIa
Device Group:	R040101 - ANTIBACTERIAL AND ANTIVIRAL RESPIRATORY FILTERS
Intended Purpose:	-/-

The validity of this certificate depends on conditions and/or is limited to the following: -/-

Revision History:

Rev.	Dated	Report	Description
00	2021-12-06	JA1613888	-
01	2023-02-03	JA63392464	-
02	2023-04-17	JA63392435	Supplemented: Device(s)/group of device(s) added

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 010815 0039 Rev. 02

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