Humidifier accessories for reusable systems

Product Code	Description	Quantity	
900MR858	MR850 inspiratory heater wire adapter	1 each	

Reusable humidification chambers

Product Code	Description	Quantity	
MR370	Adult humidification chamber	1 each	
MR340X	Infant/Neonatal humidification chamber "X" indicates regional variation	1 each	

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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

Date, **2021-11-11**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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. 04

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, Certification, Validation and Verification Regulations 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. 04

Report No.: JA200350001444

Preceding Certificate No.: G10 010815 0039 Rev. 03

Valid from: 2024-04-10
Valid until: 2026-12-05

Date of Initial Issuance: 2021-12-06

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-04-10

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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. 04

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:	-/-
Classification:	Class IIa
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	-/-
Classification:	Class IIa
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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. 04

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
03	2024-01-17	JA65712311	Supplemented: Device(s)/group of device(s) added
04	2024-04-10	JA200350001444	Supplemented: Device(s)/group of device(s) added

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®