



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	



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



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



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. 00

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. 00

Report No.: JA1613888

Valid from: 2021-12-06

Valid until: 2026-12-05

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-12-06



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. 00

Classification: IIb
Device Group: R060201 - ACTIVE VENTILATION HUMIDIFICATION SYSTEMS,
Intended Purpose: To provide heat and humidity to respiratory gases delivered to patients

Classification: IIa
Device Group: R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose: -/-

Classification: IIa
Device Group: R030101 - VENTILATION MASKS
Intended Purpose: -/-

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