



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



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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: -/-



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 BS-MDR-099



Product Service

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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