

EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Parker Hannifin Corp.

245 Township Line Road, Hatfield, Pennsylvania, 19440, United States

Manufacturer SRN: To be confirmed

Authorised Representative Name

Emergo Europe B.V

Westervoortsedijk 60, 6827 AT Arnhem, Netherlands

Scope:

- Medical gas sedation system with accessories

Certificate Number:

28620192556

Revision:

00

Initial Certification Date:

27 September 2024

Certificate Decision Date:

27 September 2024

Certificate Issue Date:

27 September 2024

Certificate Expiry Date:

11 August 2029



Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	TD00336-003 Parker Hannifin Corporation Digital MDM Flowmeter with Bag Tee, International
Audit Report Reference	Stage 1 audit ACTY-2022-615016
	Stage 2 audit ACTY-2022-541186
	Surveillance audit ACTY-2022-541188

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620192556	27 September 2024	Initial Certificate

Certificate Number:
28620192556

Revision:
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PRODUCT LIST FOR CERTIFICATE

Issued to: Parker Hannifin Corporation
Certificate number: 28620192556
Certificate valid from: 2024-09-27

Product List Issue Date:
 27 September 2024

Product	Classification and EMDN	Intended use ¹	Date Added
Medical gas sedation system with accessories			
<i>Basic UDI-DI: 081671102DMDM5N</i>			
40151602 - Digital MDM Flowmeter	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
40151602SPAIN - Digital MDM Flowmeter, Spain	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
40151604 - Digital MDM Flowmeter, Germany	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
40151614 - Digital MDM Flowmeter, Sweden	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
40151615 - Digital MDM Flowmeter, Australia	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
40151616 - Digital MDM Flowmeter, Dutch	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
40151617 - Digital MDM Flowmeter, Canada	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
40151618 - Digital MDM Flowmeter, Italy	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525176 - Digital MDM Flowmeter with Bag Tee, International	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27

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Product	Classification and EMDN	Intended use ¹	Date Added
91525178 - Digital MDM Flowmeter with Bag Tee, Germany	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525179 - Digital MDM Flowmeter with Bag Tee, Spain	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525180 - Digital MDM Flowmeter with Bag Tee, Sweden	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525182 - Digital MDM Flowmeter with Bag Tee, Israel	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525184 - Digital MDM Flowmeter with Bag Tee, Australia	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525185 - Digital MDM Flowmeter with Bag Tee, Dutch	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525186 - Digital MDM Flowmeter with Bag Tee, Canada	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525187 - Digital MDM Flowmeter with Bag Tee, Elbow Fittings	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525262 - Digital MDM Flowmeter with Bag Tee, Italy	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
91525265 - Digital MDM Flowmeter with Bag Tee, Middle East	Class IIb R9099	The Digital MDM Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide and oxygen gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic mixture percentage system	2024-09-27
Basic UDI-DI: 081671102MIDAS3T			
6030-EAVS - Midas Flowmeter, Bag Tee, Portable, 50% Max, O2 Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27

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Product	Classification and EMDN	Intended use ¹	Date Added
6030 - Midas Flowmeter with Bag Tee, Portable, 50% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6040-EAVS - Midas Flowmeter, Bag Tee, Portable, 60% Max, O2 Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6040 - Midas Flowmeter with Bag Tee, Portable, 60% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6042-EAVS - Midas Flowmeter, Bag Tee, Portable, 60% Max, O2 Control, Sweden+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6042 - Midas Flowmeter with Bag Tee, Portable, 60% Max, O2 Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6050-EAVS - Midas Flowmeter, Bag Tee, Portable, 70% Max, O2 Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6050 - Midas Flowmeter with Bag Tee, Portable, 70% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6051-EAVS - Midas Flowmeter, Bag Tee, Portable, 70% Max, O2 Control, Australia+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6051 - Midas Flowmeter with Bag Tee, Portable, 70% Max, O2 Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27

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6060-EAVS - Midas Flowmeter, Bag Tee, Portable, 50% Max, N2O Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6060 - Midas Flowmeter with Bag Tee, Portable, 50% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6070-EAVS - Midas Flowmeter, Bag Tee, Portable, 60% Max, N2O Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6070 - Midas Flowmeter with Bag Tee, Portable, 60% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6072-EAVS - Midas Flowmeter, Bag Tee, Portable, 60% Max, N2O Control, Sweden+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6072 - Midas Flowmeter with Bag Tee, Portable, 60% Max, N2O Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6080-EAVS - Midas Flowmeter, Bag Tee, Portable, 70% Max, N2O Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6080 - Midas Flowmeter with Bag Tee, Portable, 70% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6081-EAVS - Midas Flowmeter, Bag Tee, Portable, 70% Max, N2O Control, Australia+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27

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Product	Classification and EMDN	Intended use ¹	Date Added
6081 - Midas Flowmeter with Bag Tee, Portable, 70% Max, N2O Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6130-EAVS - Midas Flowmeter, Bag Tee, Remote, 50% Max, O2 Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6130 - Midas Flowmeter with Bag Tee, Remote, 50% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6140-EAVS - Midas Flowmeter, Bag Tee, Remote, 60% Max, O2 Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6140 - Midas Flowmeter with Bag Tee, Remote, 60% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6142-EAVS - Midas Flowmeter, Bag Tee, Remote, 60% Max, O2 Control, Sweden+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6142 - Midas Flowmeter with Bag Tee, Remote, 60% Max, O2 Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6150-EAVS - Midas Flowmeter, Bag Tee, Remote, 70% Max, O2 Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6150 - Midas Flowmeter with Bag Tee, Remote, 70% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27

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6151-EAVS - Midas Flowmeter, Bag Tee, Remote, 70% Max, O2 Control, Australia + eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6151 - Midas Flowmeter with Bag Tee, Remote, 70% Max, O2 Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6160-EAVS - Midas Flowmeter, Bag Tee, Remote, 50% Max, N2O Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6160 - Midas Flowmeter with Bag Tee, Remote, 50% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6170-EAVS - Midas Flowmeter, Bag Tee, Remote, 60% Max, N2O Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6170 - Midas Flowmeter with Bag Tee, Remote, 60% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6172-EAVS - Midas Flowmeter, Bag Tee, Remote, 60% Max, N2O Control, Sweden+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6172 - Midas Flowmeter with Bag Tee, Remote, 60% Max, N2O Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6180-EAVS - Midas Flowmeter, Bag Tee, Remote, 70% Max, N2O Control+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27

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6180 - Midas Flowmeter with Bag Tee, Remote, 70% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
6181-EAVS - Midas Flowmeter, Bag Tee, Remote, 70% Max, N2O Control, Australia+ eAVS	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. When used with the Electronic Automatic Vacuum Switch (eAVS), the Midas Flowmeter is used to control the scavenging flow rate for exhaled waste analgesic gas. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system. When used with eAVS, the device features vacuum flowrate control on the Midas Flowmeter Touchscreen.	2024-09-27
6181 - Midas Flowmeter with Bag Tee, Remote, 70% Max, N2O Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6030 - Midas Flowmeter, Portable, 50% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6040 - Midas Flowmeter, Portable, 60% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6042 - Midas Flowmeter, Portable, 60% Max, O2 Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6050 - Midas Flowmeter, Portable, 70% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6051 - Midas Flowmeter, Portable, 70% Max, O2 Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6060 - Midas Flowmeter, Portable, 50% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6070 - Midas Flowmeter, Portable, 60% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6072 - Midas Flowmeter, Portable, 60% Max, N2O Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6080 - Midas Flowmeter, Portable, 70% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Product	Classification and EMDN	Intended use ¹	Date Added
MFCM-6081 - Midas Flowmeter, Portable, 70% Max, N2O Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6130 - Midas Flowmeter, Remote, 50% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6140 - Midas Flowmeter, Remote, 60% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6142 - Midas Flowmeter, Remote, 60% Max, O2 Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6150 - Midas Flowmeter, Remote, 70% Max, O2 Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6151 - Midas Flowmeter, Remote, 70% Max, O2 Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6160 - Midas Flowmeter, Remote, 50% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6170 - Midas Flowmeter, Remote, 60% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6172 - Midas Flowmeter, Remote, 60% Max, N2O Control, Sweden	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6180 - Midas Flowmeter, Remote, 70% Max, N2O Control	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27
MFCM-6181 - Midas Flowmeter, Remote, 70% Max, N2O Control, Australia	Class IIb R9099	The Midas Flowmeter is intended for use as a continuous flow system to deliver a mixture of nitrous oxide (N2O) and oxygen (O2) gases to a conscious, spontaneously breathing patient. The device controls the flowrate of nitrous oxide and oxygen medical gases using an electronic, software driven system	2024-09-27

¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

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