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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.

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

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

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
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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

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27 September 2024

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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:
19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Medical gas sedation system with accessories			
Basic UDI-DI: 081671102AVSCX			
AVS-5000 - Automatic Vacuum Switch with Adapter Hoses and Vacuum Tube Holder	Class IIa R030180		2024-12-19
AVS-5000B - Automatic Vacuum Switch with Bracket Mount	Class IIa R030180		2024-12-19
AVS-5000C - Automatic Vacuum Switch with Ball Mount	Class IIa R030180		2024-12-19
AVS-5000QD - Automatic Vacuum Switch with Quick Disconnect	Class IIa R030180		2024-12-19
AVS-5000S - Automatic Vacuum Switch with Swivel Mount	Class IIa R030180		2024-12-19
Basic UDI-DI: 081671102BAGAD			
4100-2NL - 2 Liter Breathing or Reservoir Bag	Class IIa R9080		2024-12-19
4100-3NL - 3 Liter Breathing or Reservoir Bag	Class IIa R9080		2024-12-19
Basic UDI-DI: 081671102BAGTEEVZ			
30157400 - Bag Tee for DMDM Flowmeter	Class IIa R9080		2024-12-19
C1777-000 - Bag Tee for Midas Portable Flowmeter	Class IIa R9080		2024-12-19
C1777-001 - Bag Tee for Midas Remote Flowmeter	Class IIa R9080		2024-12-19
P1407A - Bag Tee for MXR Flowmeter and MDM Flowmeter	Class IIa R9080		2024-12-19
P1407B - Bag Tee for MXR Flowmeter and MDM Flowmeter with Retrofit Adapter	Class IIa R9080		2024-12-19
P1407E - Bag Tee with Adapter	Class IIa R9080		2024-12-19
P1407QD - Bag Tee For MXR and MDM Flowmeter with Quick Disconnect	Class IIa R9080		2024-12-19

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

Product	Classification and EMDN	Intended use[1]	Date Added
Basic UDI-DI: 081671102DMDM5N			
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
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

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

Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
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: 081671102EAVS63			
EAVS-5000 - Midas Scavenger	Class IIa R030180		2024-12-19
Basic UDI-DI: 081671102MATRXCIRCUITZP			
82501 - Matrx Breathing Circuit, Pediatric with 3L Breathing Bag	Class IIa R020199		2024-12-19
82502 - Matrx Breathing Circuit, Medium with 3L Breathing Bag	Class IIa R020199		2024-12-19
82503 - Matrx Breathing Circuit, Large with 3L Breathing Bag	Class IIa R020199		2024-12-19
82504 - Matrx Breathing Circuit, Pediatric with 3L Breathing Bag and Scavenger Control Valve	Class IIa R020199		2024-12-19
82505 - Matrx Breathing Circuit, Medium with 3L Breathing Bag and Scavenger Control Valve	Class IIa R020199		2024-12-19
82506 - Matrx Breathing Circuit, Large with 3L Breathing Bag and Scavenger Control Valve	Class IIa R020199		2024-12-19

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

Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
91316461 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316462 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316463 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316464 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316465 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316466 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Small, 24 Pack	Class IIa R030199		2024-12-19
91316468 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316469 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316470 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316471 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316472 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316473 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316475 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316476 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316477 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316478 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
91316479 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316480 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Large, 24 Pack	Class IIa R030199		2024-12-19
91316481 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Multiple Sizes, 24 Pack	Class IIa R030199		2024-12-19
91316482 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316483 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316484 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316485 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316486 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Small, 24 Pack	Class IIa R030199		2024-12-19
91316487 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Small, 24 Pack	Class IIa R030199		2024-12-19
91316489 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316490 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316491 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316492 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316493 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Large, 24 Pack	Class IIa R030199		2024-12-19
91316494 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Large, 24 Pack	Class IIa R030199		2024-12-19
91316495 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Multiple Sizes, 24 Pack	Class IIa R030199		2024-12-19

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
91316496 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Small, 12 Pack	Class IIa R030199		2024-12-19
91316497 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Small Model, 12 Pack	Class IIa R030199		2024-12-19
91316498 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Small, 12 Pack	Class IIa R030199		2024-12-19
91316499 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Small, 12 Pack	Class IIa R030199		2024-12-19
91316500 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Small, 12 Pack	Class IIa R030199		2024-12-19
91316501 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Small, 12 Pack	Class IIa R030199		2024-12-19
91316503 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Medium, 12 Pack	Class IIa R030199		2024-12-19
91316504 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Medium, 12 Pack	Class IIa R030199		2024-12-19
91316505 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Medium, 12 Pack	Class IIa R030199		2024-12-19
91316506 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Medium, 12 Pack	Class IIa R030199		2024-12-19
91316507 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Medium, 12 Pack	Class IIa R030199		2024-12-19
91316508 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Medium, 12 Pack	Class IIa R030199		2024-12-19
91316510 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Large, 12 Pack	Class IIa R030199		2024-12-19
91316511 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Large, 12 Pack	Class IIa R030199		2024-12-19
91316512 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Large, 12 Pack	Class IIa R030199		2024-12-19
91316513 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Large, 12 Pack	Class IIa R030199		2024-12-19

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
91316514 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Large, 12 Pack	Class IIa R030199		2024-12-19
91316515 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Large, 12 Pack	Class IIa R030199		2024-12-19
91316516 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Multiple Sizes, 12 Pack	Class IIa R030199		2024-12-19
91316519 - Matrx Disposable DynoMite Nasal Hood, Bubblegum Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316520 - Matrx Disposable DynoMite Nasal Hood, Strawberry Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316521 - Matrx Disposable DynoMite Nasal Hood, Orange Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316522 - Matrx Disposable DynoMite Nasal Hood, Vanilla Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316523 - Matrx Disposable DynoMite Nasal Hood, Plain Flavor, Medium, 24 Pack	Class IIa R030199		2024-12-19
91316524 - Matrx Disposable DynoMite Nasal Hood, Assorted Flavors, Medium, 24 Pack	Class IIa R030199		2024-12-19
91515094 - Matrx Reusable Nasal Hood, Pediatric	Class IIa R030199		2024-12-19
91515095 - Matrx Reusable Nasal Hood, Medium	Class IIa R030199		2024-12-19
91515096 - Matrx Reusable Nasal Hood, Large	Class IIa R030199		2024-12-19
91515142 - Universal Conversion Package: Matrx Disposable DynoMite Nasal Hood, Large, Breathing Circuit Adapter	Class IIa R030199		2024-12-19
91515192 - Matrx Breathing Circuit with Matrx Reusable Nasal Hood, Large	Class IIa R020199		2024-12-19
91515193 - Matrx Breathing Circuit with Matrx Reusable Nasal Hood, Medium	Class IIa R020199		2024-12-19
91515194 - Matrx Breathing Circuit with Matrx Reusable Nasal Hood, Pediatric	Class IIa R020199		2024-12-19
91515197 - Matrx Breathing Circuit	Class IIa R020199		2024-12-19

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Basic UDI-DI: 081671102MDMCR			
91500167 - MDM Flowmeter, Canada	Class IIb R9099	The 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 flow of nitrous oxide and oxygen medical gases using a dial mixture percentage system	2024-11-29
91500333 - MDM Flowmeter France	Class IIb R9099	The 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 flow of nitrous oxide and oxygen medical gases using a dial mixture percentage system	2024-11-29
91500401 - MDM Flowmeter Sweden	Class IIb R9099	The 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 flow of nitrous oxide and oxygen medical gases using a dial mixture percentage system	2024-11-29
94500011 - MDM Flowmeter, Standard	Class IIb R9099	The 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 flow of nitrous oxide and oxygen medical gases using a dial mixture percentage system	2024-11-29
94500150 - MDM Flowmeter, Standard International	Class IIb R9099	The 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 flow of nitrous oxide and oxygen medical gases using a dial mixture percentage system	2024-11-29
94500150SPAIN - MDM Flowmeter, Spain	Class IIb R9099	The 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 flow of nitrous oxide and oxygen medical gases using a dial mixture percentage system	2024-11-29
94500323 - MDM Flowmeter, Australia	Class IIb R9099	The 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 flow of nitrous oxide and oxygen medical gases using a dial mixture percentage system	2024-11-29
Basic UDI-DI: 081671102MEDICALCIRCUIT4J			
1550 - Porter Face Mask, Pediatric	Class IIa R030199		2024-12-19
1575-1 - Porter Face Mask, Adult	Class IIa R030199		2024-12-19
61988000 - Mouthpiece	Class IIa R030199		2024-12-19
93316426 - Matrx Facemask, Pediatric	Class IIa R030199		2024-12-19
93316427 - Matrx Facemask, Adult	Class IIa R030199		2024-12-19
DMC-12 - Medical Breathing Circuit, 12 Pack	Class IIa R020199		2024-12-19
DMC-5301-6 - Medical Breathing Circuit, 10 Pack	Class IIa R020199		2024-12-19
DMC-LARGE - Face Mask, Large	Class IIa R030199		2024-12-19
DMC-MEDIUM - Face Mask, Medium	Class IIa R030199		2024-12-19

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
DMC-PEDO - Face Mask, Pediatric	Class IIa R030199		2024-12-19
DMC-SMALL - Face Mask, Small	Class IIa R030199		2024-12-19
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 Flowmwter Touchscreen.	2024-09-27
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 Flowmwter 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 Flowmwter 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 Flowmwter 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

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
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 Flowmwter 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
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 Flowmwter 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 Flowmwter 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 Flowmwter 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 Flowmwter Touchscreen.	2024-09-27

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
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 Flowmwter Touchscreen.	2024-09-27
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 Flowmwter 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 Flowmwter 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 Flowmwter 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

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
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 Flowmwter 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
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 Flowmwter 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 Flowmwter 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 Flowmwter 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 Flowmwter Touchscreen.	2024-09-27

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
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 Flowmwter Touchscreen.	2024-09-27
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 Flowmwter 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

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
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
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

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
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
Basic UDI-DI: 081671102MOUNTINGZH			
2040 - Mobile Stand, Short	Class IIa R9080		2024-12-19
2042 - Mobile Stand, Tall	Class IIa R9080		2024-12-19
2044 - Mobile Stand, Extra Tall	Class IIa R9080		2024-12-19
2045-3ISO - E-Stand, Tall with Gas Supply Hoses	Class IIa R9080		2024-12-19
2045-SHORT3-ISO - E-Stand, Short with Gas Supply Hoses	Class IIa R9080		2024-12-19
2100 - 2-Cylinder Mobile Cart	Class IIa R9080		2024-12-19
2100-ISO-2 - 2-Cylinder Mobile Cart with Regulator, O2, Regulator, N2O, and Gas Supply Hoses	Class IIa R9080		2024-12-19
2100-ISO-N - 2-Cylinder Mobile Cart with Regulator, N2O, and Gas Supply Hose	Class IIa R9080		2024-12-19
Basic UDI-DI: 081671102MXREX			
C3000 - MXR Flowmeter, 70% N2O	Class IIb R9099	The MXR 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 flow of nitrous oxide and oxygen medical gases using needle valves and precision glass tube system	2024-11-29
C3050 - MXR Flowmeter, 50% N2O	Class IIb R9099	The MXR 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 flow of nitrous oxide and oxygen medical gases using needle valves and precision glass tube system	2024-11-29
Basic UDI-DI: 081671102NOXPLUSNW			
NOX-PLUS-050 - Nitronox Plus Demand System, 0-50% N2O	Class IIb R9099	The Nitronox Plus is intended to provide a mixture of nitrous oxide and oxygen gas, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates	2024-12-19
NOX-PLUS-070 - Nitronox Plus Demand System, 0-70% N2O	Class IIb R9099	The Nitronox Plus is intended to provide a mixture of nitrous oxide and oxygen gas, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates	2024-12-19
NOX-PLUS-5050 - Nitronox Plus Demand System, 50/50% N2O/O2	Class IIb R9099	The Nitronox Plus is intended to provide a mixture of nitrous oxide and oxygen gas, on demand, to a conscious, spontaneously breathing patient. The Nitronox Plus is designed for use with adult and pediatric patients and is not intended to be used with infants or neonates	2024-12-19
Basic UDI-DI: 081671102PORTERCIRCUITJC			

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
5053AD12C - Porter Disposable Nasal Hood Liner, Adult, Citrus 12 Pack	Class IIa R030199		2024-12-19
5053AD12 - Porter Disposable Nasal Hood Liner, Adult, 12 Pack	Class IIa R030199		2024-12-19
5053AD144C - Porter Disposable Nasal Hood Liner, Adult, Citrus 144 Pack	Class IIa R030199		2024-12-19
5053AD144 - Porter Disposable Nasal Hood Liner, Adult, 144 Pack	Class IIa R030199		2024-12-19
5053PD12C - Porter Disposable Nasal Hood Liner, Pediatric, Citrus 12 Pack	Class IIa R030199		2024-12-19
5053PD12 - Porter Disposable Nasal Hood Liner, Pediatric, 12 Pack	Class IIa R030199		2024-12-19
5053PD144C - Porter Disposable Nasal Hood Liner, Pediatric, Citrus, 144 Pack	Class IIa R030199		2024-12-19
5053PD144 - Porter Disposable Nasal Hood Liner, Pediatric, 144 Pack	Class IIa R030199		2024-12-19
5054-1 - Porter, Reusable Nasal Hood Liner, Adult, 3 Pack	Class IIa R030199		2024-12-19
5054-2 - Porter Reusable Nasal Hood Liner, Pediatric, 3 Pack	Class IIa R030199		2024-12-19
5054A - Porter Reusable Nasal Hood, Adult with Porter Reusable Nasal Hood Liner, Adult, 3 Pack	Class IIa R030199		2024-12-19
5054B - Porter Reusable Nasal Hood, Pediatric with Porter Reusable Nasal Hood Liners, Pediatric, 3 Pack	Class IIa R030199		2024-12-19
5054C - Porter Reusbale Nasal Hood, Adult with Porter Reusbale Nasal Hood Liner, Adult, 1 Pack	Class IIa R030199		2024-12-19
5054D - Porter Reusable Nasal Hood, Pediatric with Porter Reusbale Nasal Hood Liner, Pediatric, 1 Pack	Class IIa R030199		2024-12-19
5059-010 - Vacuum Tubing, Grey (10 ft Length)	Class IIa R020199		2024-12-19
5059 - Vacuum Tubing, Grey (8 ft Length)	Class IIa R020199		2024-12-19
5060-3 - Fresh Gas Extension Tubing, Short	Class IIa R020199		2024-12-19
5060-6 - Fresh Gas Extension Tubing, Long	Class IIa R020199		2024-12-19
5155-1 - Porter Breathing Circuit, Adult with In-line Vacuum Block	Class IIa R020199		2024-12-19
5155-2 - Porter Breathing Circuit, Pediatric with In-line Vacuum Block	Class IIa R020199		2024-12-19
5155-3 - Porter Breathing Circuit, Adult	Class IIa R020199		2024-12-19
5155-4 - Porter Breathing Circuit, Pediatric	Class IIa R020199		2024-12-19

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Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
91525191 - Directional Valve Package: Y Valve, Non-rebreathing Valve, Universal Adapter, Pediatric/Adult Face Mask, Extension Tubing	Class IIa R030199		2024-12-19
PA-679-000 - Vacuum Tubing, Grey (Variable Length)	Class IIa R020199		2024-12-19
PA-679-CLR25 - Vacuum Tubing, Clear (25 ft Length)	Class IIa R020199		2024-12-19
PA-679-CLR - Vacuum Tubing, Clear (20 ft Length)	Class IIa R020199		2024-12-19
Basic UDI-DI: 081671102SCAVPLUSSB			
5400SCAVPLUS - Scavenger Plus	Class IIa		2024-12-19
Basic UDI-DI: 081671102SILHOUETTE72			
B-5581-001 - Fresh Gas and Vacuum Tubing	Class IIa R020199		2024-12-19
C-1734-LG - Silhouette Circuit, Large	Class IIa R020199		2024-12-19
C-1734-MD - Silhouette Circuit, Medium	Class IIa R020199		2024-12-19
C-1734-PD - Silhouette Circuit, Pediatric	Class IIa R020199		2024-12-19
C-1734-SM - Silhouette Circuit, Small	Class IIa R020199		2024-12-19
C-1781-LG - Silhouette 2 Circuit, Large	Class IIa R020199		2024-12-19
C-1781-MD - Silhouette 2 Circuit, Medium	Class IIa R020199		2024-12-19
C-1781-PD - Silhouette 2 Circuit, Pediatric	Class IIa R020199		2024-12-19
C-1781-SM - Silhouette 2 Circuit, Small	Class IIa R020199		2024-12-19
SIL2-LG-12 - Silhouette 2 Circuit, Large, 12 Pack	Class IIa R020199		2024-12-19
SIL2-LG-144 - Silhouette 2 Circuit, Large 144 Pack	Class IIa R020199		2024-12-19
SIL2-LG-24 - Silhouette 2 Circuit, Large, 24 Pack	Class IIa R020199		2024-12-19
SIL2-MED-12 - Silhouette 2 Circuit, Medium, 12 Pack	Class IIa R020199		2024-12-19
SIL2-MED-144 - Silhouette 2 Circuit, Medium, 144 Pack	Class IIa R020199		2024-12-19
SIL2-MED-24 - Silhouette 2 Circuit, Medium, 24 Pack	Class IIa R020199		2024-12-19
SIL2-PEDO-12 - Silhouette 2 Circuit, Pediatric, 12 Pack	Class IIa R020199		2024-12-19

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Certificate number: 28620192556
Product list issue date: 19 December 2024

Product	Classification and EMDN	Intended use[1]	Date Added
SIL2-PEDO-144 - Silhouette 2 Circuit, Pediatric, 144 Pack	Class IIa R020199		2024-12-19
SIL2-PEDO-24 - Silhouette 2 Circuit, Pediatric, 24 Pack	Class IIa R020199		2024-12-19
SIL2-RETRO-PKG - Connector Package: Sizer Masks, Vacuum Block Adjuster, Breathing Bag Cap, Fresh Gas-Vacuum Tubing	Class IIa R020199		2024-12-19
SIL2-SM-12 - Silhouette 2 Circuit, Small, 12 Pack	Class IIa R020199		2024-12-19
SIL2-SM-144 - Silhouette 2 Circuit, Small, 144 Pack	Class IIa R020199		2024-12-19
SIL2-SM-24 - Silhouette 2 Circuit, Small, 24 Pack	Class IIa R020199		2024-12-19
SIL2-VAR-4x3 - Silhouette 2 Circuit, 3 of Each Size, 12 Pack	Class IIa R020199		2024-12-19
SIL-ADPT-KIT - Adapter Package: Cannula Adaptor, Clip with Strap, Bag Tee Cap	Class IIa R020199		2024-12-19
SIL-ADPT-PKG - Adapter Package: Cannula Adaptor, Clip with Strap, Bag Tee Cap	Class IIa R020199		2024-12-19
SIL-CONN-KIT - Connector Package: Cannula Adaptor, Breathing Bag Cap, Fresh Gas-Vacuum Tubing, 4 Sizer Masks, Clip	Class IIa R020199		2024-12-19
SIL-LG-12 - Silhouette Circuit, Large, 12 Pack	Class IIa R020199		2024-12-19
SIL-LG-144 - Silhouette Circuit, Large 144 Pack	Class IIa R020199		2024-12-19
SIL-LG-24 - Silhouette Circuit, Large, 24 Pack	Class IIa R020199		2024-12-19
SIL-MED-12 - Silhouette Circuit, Medium, 12 Pack	Class IIa R020199		2024-12-19
SIL-MED-144 - Silhouette Circuit, Medium, 144 Pack	Class IIa R020199		2024-12-19
SIL-MED-24 - Silhouette Circuit, Medium, 24 Pack	Class IIa R020199		2024-12-19
SIL-PEDO-12 - Silhouette Circuit, Pediatric, 12 Pack	Class IIa R020199		2024-12-19
SIL-PEDO-144 - Silhouette Circuit, Pediatric, 144 Pack	Class IIa R020199		2024-12-19
SIL-PEDO-24 - Silhouette Circuit, Pediatric, 24 Pack	Class IIa R020199		2024-12-19
SIL-SIZER-4 - Sizers, 4 Pack (1 of Each Size)	Class IIa R020199		2024-12-19
SIL-SM-12 - Silhouette Circuit, Small, 12 Pack	Class IIa R020199		2024-12-19

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Certificate number: 28620192556
Product list issue date: 19 December 2024

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SIL-SM-144 - Silhouette Circuit, Small, 144 Pack	Class IIa R020199		2024-12-19
SIL-SM-24 - Silhouette Circuit, Small, 24 Pack	Class IIa R020199		2024-12-19
SIL-START-PK - Starter Package: 3 Silhouette Circuits of each size, Cannula Adaptor, Breathing Bag Cap, Fresh Gas-Vacuum Tubing	Class IIa R020199		2024-12-19
SIL-VAR-4X3 - Silhouette Circuit, 3 of Each Size, 12 Pack	Class IIa R020199		2024-12-19
Basic UDI-DI: 081671102SUPPLYHOSESMZ			
80610-ISO - Gas Supply Hose, O2, DISS ØISS Fittings (10 Ft Length)	Class IIa R9080		2024-12-19
80615-ISO - Gas Supply Hose, O2, DISS ØISS Fittings (15 Ft Length)	Class IIa R9080		2024-12-19
8063-ISO - Gas Supply Hose, O2, DISS / DISS Fittings (3 Ft Length)	Class IIa R9080		2024-12-19
8065-ISO - Gas Supply Hose, O2, DISS / DISS Fittings (5 Ft Length)	Class IIa R9080		2024-12-19
85010 - Gas Supply Hose, N2O, DISS / DISS Fittings (10 Ft Length)	Class IIa R9080		2024-12-19
85012 - Gas Supply Hose, N2O, DISS / DISS Fittings (12 Ft Length)	Class IIa R9080		2024-12-19
85015 - Gas Supply Hose, N2O, DISS / DISS Fittings (15 Ft Length)	Class IIa R9080		2024-12-19
8503 - Gas Supply Hose, N2O, DISS / DISS Fittings (3 Ft Length)	Class IIa R9080		2024-12-19
8505 - Gas Supply Hose, N2O, DISS / DISS Fittings (5 Ft Length)	Class IIa R9080		2024-12-19
92305291-10 - Gas Supply Hose, O2, Matrx-M/DISS-F Fittings (10 ft Length)	Class IIa R9080		2024-12-19
92305291-15 - Gas Supply Hose, O2, Matrx-M/DISS-F Fittings (15 ft Length)	Class IIa R9080		2024-12-19
92305291-3 - Gas Supply Hose, O2, Matrx-M/DISS-F Fittings (3 ft Length)	Class IIa R9080		2024-12-19
92305291-5 - Gas Supply Hose, O2, Matrx-M/DISS-F Fittings (5 ft Length)	Class IIa R9080		2024-12-19
92305297-10 - Gas Supply Hose, O2, DISS-F / DISS-F Fittings (10 ft Length)	Class IIa R9080		2024-12-19
92305297-12 - Gas Supply Hose, O2, DISS-F / DISS-F Fittings (12 ft Length)	Class IIa R9080		2024-12-19
92305297-15 - Gas Supply Hose, O2, DISS-F / DISS-F Fittings (15 ft Length)	Class IIa R9080		2024-12-19
92305297-3 - Gas Supply Hose, O2, DISS-F / DISS-F Fittings (3 ft Length)	Class IIa R9080		2024-12-19
92305297-5 - Gas Supply Hose, O2, DISS-F / DISS-F Fittings (5 ft Length)	Class IIa R9080		2024-12-19

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Product list issue date: 19 December 2024

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Basic UDI-DI: 081671102VACUUM7H			
5501-RK - Porter In-line Vacuum Control Block	Class IIa R030180		2024-12-19
91515083 - Matrx Scavenger Control Valve for MDM Flowmeter	Class IIa R030180		2024-12-19
91515085 - Matrx Scavenger Control Valve with Quick Connect Adapter	Class IIa R030180		2024-12-19
91515086 - Matrx Scavenger Control Valve with Cabinet Mount	Class IIa R030180		2024-12-19
91525109 - Matrx Scavenger Control Valve for Digital MDM Flowmeter	Class IIa R030180		2024-12-19

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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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