1. Device identification and general information	
Trade Name of the Device (s):	mem*sorb*™
Product codes:	MS-DR (for Dräger anaesthesia machines) MS-GE (for GE anaesthesia machines)
Manufacturer's Name:	DMF Medical Incorporated
Manufacturer's Address:	1 Research Drive Dartmouth, Nova Scotia Canada, B2Y 4M9
SRN (Single Registration Number):	CA-MF-000038004
Basic UDI-DI:	754016236
GMN Codes:	42414
Medical device nomenclature description:	R9099 - Respiratory and Anaesthesia Devices – Other
Classification:	Class IIa non-implantable as per Rule 2 and Rule 3 of Annex VIII
CE Certificate Year of Issue	MDR 766014 (2024)
Authorized Representative Name:	OBELIS S.A
Authorized Representative Address:	Bd. Général Wahis, 53 1030 Brussels, Belgium
Authorized Representative SRN:	BE-AR-000000106
Notified Body name:	BSI Group The Netherlands B.V.
Notified Body Address:	Say Building, John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands
Notified Body Single Identification number:	2797

2. Intended use of the device	
Intended Purpose:	memsorb™ is intended to remove carbon dioxide (CO_2) from the breathing systems of anesthetic workstations.
Indication(s) and target population(s):	memsorb™ can be used to remove CO_2 during general anesthesia procedures that utilize the following anesthetic vapors: desflurane and sevoflurane. memsorb™ is made of inert materials and does not react with anesthetic agents, therefore it may be used with no fresh gas flow restrictions. memsorb™ may also be used to remove CO_2 during general anesthesia procedures that utilize intravenous or total intravenous anesthesia. memsorb™ is compatible with the following anesthesia machines: Dräger Medical models: Fabius, Perseus, Primus, and Zeus. GE Healthcare model: Aisys. memsorb™ is for use in populations 18 years of age and older
Contraindications and/or limitations:	memsorb™ is not intended to be used with Nitrous Oxide.

3. Device description	
Description of the device:	memsorb™, a carbon dioxide (CO_2) filter, consists of an impact resistant, recyclable and BPA free plastic (Tritan™) shell that houses an inner polymeric (polymethylpentene) hollow fiber membrane. The outer shell is equipped with a machine specific top connector that allows it to replace the existing CO_2 absorbers that are used on the anaesthetic machine.
Previous generation(s) or variants if such exist, and a description of the differences:	There are no previous generations There are two variants of memsorb™: MS-DR for use with Dräger anaesthesia machines MS-GE for use with GE anaesthesia machines
Description of any accessories which are intended to be used in combination with the device:	- Heat and moisture exchanger with bacterial and viral filter (HMEF) - Medical oxygen (O_2) and medical air supply for connecting to the blender - Medical air-oxygen blender able to provide 21 to 100 % medical oxygen in medical air - A flow meter with the ability to maintain and display the blender flow rate of 13 to 15 Liters per minute (Lpm) - 1/4" tubing for connecting flow meter output to memsorb™ - Scavenging system that is capable of handling a minimum flow rate of 15 Lpm - For passive scavenging systems: 30 mm (ANSI Standard) hose or a same-size adapter for connecting memsorb™ to the scavenging system - For passive scavenging systems: a scavenging pressure relief valve that conforms to ISO 80601-2- 13 - For active scavenging systems: 5/16" tubing for connecting memsorb™ to the scavenging system - Tubing adapters as necessary
Description of any other devices and products which are intended to be used in combination with the device:	Dräger anaesthesia machines GE anaesthesia machines

4. Possible diagnostic or therapeutic alternatives
The function of mem*sorb*™ is to remove CO_2 from the anaesthesia circuit via filtration, rather than via a chemical reaction, as in CO_2 absorbers. It is designed to fully replace chemical CO_2 absorbers and perform the same function. It is not a therapeutic device. mem*sorb*™ functions as expected when etCO_2 remains in the normal physiological range and the concentration of vapour remains in the clinical range ensuring the patient remains anaesthetised.

5. Harmonised standards and CS applied	
EN ISO 14971	Medical devices – Application of risk management to medical devices
EN ISO 13485	Medical device – Quality management system – Requirements for regulatory purposes

6. Summary of clinical evaluation and post-market clinical follow-up (PMCF)	
Summary of clinical data related to equivalent device, if applicable:	NA
Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable:	Studies provide evidence that: - mem*sorb*™ membrane filtration technology is equivalent to chemical CO_2 absorbers in the ability to remove CO_2 from the patient rebreathing circuit during general anesthesia procedures. - mem*sorb*™ membrane filtration technology for removing CO_2 from the patient rebreathing circuit during general anesthesia procedures is a safe and effective alternative to chemical CO_2 absorbers. - memsorb™ uses membrane-based technology and therefore inspired CO_2 is not a measure of the device function. Inspired CO_2 levels in excess of 5 mmHg may be observed. Manage expired CO_2 levels as per the anaesthesia machine manufacturer's instructions. - mem*sorb*™ is installed on the anesthesia machines in the same space as current chemical CO_2 absorbers - The established performance and functionality of mem*sorb*™ is safe and effective for use when removing CO_2 from the patient rebreathing circuit during general anesthesia procedures. - A leak free installation of mem*sorb*™ is achievable on the anesthesia machines - mem*sorb*™ did not negatively impact the performance of the anaesthesia machines.
Summary of clinical data from other sources, if applicable:	An extensive literature review was performed to evaluate the state-of-the-art in CO_2 removal. The differences between mem*sorb*™ and CO_2 absorbers is related to the mechanism of action. mem*sorb*™'s mechanism of action removes CO_2 from the rebreathing circuit via diffusion across a chemically inert polymer membrane. A concentration gradient is maintained across the membrane using a continuous gas supply through the sweep compartment, which pulls the CO_2 out of the patient compartment and into the sweep gas (scavenging) compartment. The CO_2 enriched sweep gas is then fed into the scavenging system of the hospital, thereby removing it from the patient circuit. The risk of toxic by-product formation via chemical interaction of anesthetic vapours with the highly reactive granulate has been eliminated by using an inert membrane to remove CO_2.
Overall summary of the clinical performance and safety	mem*sorb*™ functions as expected when etCO_2 remains in the normal physiological range and the concentration of vapour remains in the clinical range ensuring the patient remains anaesthetised.
Ongoing or planned post-market clinical follow-up	Post-market clinical follow-up studies are not deemed necessary at this time.

7. Suggested profile and training for users
For Professional Use Only memsorb™ must be used under the constant supervision and attention of qualified health care professionals trained in the use of anaesthesia machines.

8. Risks and warnings	
Residual risks and undesirable effects:	There are no side effects as memsorb™ is not intended for treatment of specific clinical conditions. The risk of using the CO_2 removal filter, memsorb™, is very low since the device is used under the direct supervision and monitoring of qualified health professionals. In the event of a complete device failure, general anesthesia can be performed in the absence of any carbon dioxide removal device. The following risks were identified that required actions to mitigate these risks: - Risk of interoperative awareness due to device leaks. o Events leading to risk: Cracks in the housing or delamination of the glue could lead to leaks and loss of anaesthetic vapour. o Mitigation: Perform leak test prior to use. - Risk of hypercapnia due to membrane fiber occlusions or defects. o Events leading to risk: Occluded or defective fibers could prevent the removal of CO_2 from the breathing circuit. o Mitigation: Each device is tested for CO_2 removal prior to release to market and device must only be used in conjunction with CO_2 monitoring. - Risk of hypercapnia due to lack of sweep gas flow. o Events leading to risk: Incorrect connection of sweep gas tubing or kinking of tubing. Loss of sweep gas flow can lead to the accumulation of CO_2 in the breathing circuit. o Mitigation: Device must only be used in conjunction with CO_2 monitoring, safe operation requires that the air-oxygen sweep gas flow must be maintained at 13 to 15 Litres per minute at all times, and passive scavenging requires the use of an in-line pressure relief value. - Risk of bacterial or viral contamination. o Events leading to risk: Bacterial and viral filter not placed in the breathing circuit. o Intended for use by trained personnel
Warnings and precautions:	- memsorb™ must be used with an air-oxygen blender. The air-oxygen concentration in the sweep gas affects the patient-gas concentration and as a result they should be matched using the blender. - mem*sorb*™ must only be used in conjunction with CO_2 monitoring. - CO_2 removal will not take place in the breathing system when mem*sorb*™ is removed. - memsorb™ is intended for use in adult populations 18 years of age and older. - Safe operation requires that the air-oxygen sweep gas flow must be maintained at 13 to 15 Litres per minute at all times. - mem*sorb*™ removes moisture from the machine-side gas mixture. - mem*sorb*™ must be used with a Heat and Moisture Exchange Filter (HMEF) installed between the patient and anesthetic circuit to retain moisture on the patient side and to prevent cross-contamination. - memsorb™ MS-DR requires a specialty functional leak test. - Do NOT attempt to sterilize or disassemble mem*sorb*™ under any circumstances. - Handle memsorb™ with care. Damage may occur if the unit is bumped or knocked
Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable:	There are no FSCAs or FSNs.

9. Other Benefits

Other benefits of using memsorb™

- eliminates the risk of exposure to dangerous caustic dust that is present in chemical CO_2 absorbers
- chemical composition is inert unlike chemical CO_2 absorbers.
- eliminates CO production
- eliminates risk of toxic by-product production unlike chemical CO_2 absorbers

10. Revision history

Version	Change description	Date issued
V01	First Issue	2023-09-19
V02	Add SRN	2024-04-22
V03	Added new SRN and GRN code, also added new warning statement to handle with care	2024-11-24