Product Information

Provox Micron HME

Product description:

Provox Micron HME is a Heat and Moisture Exchanger combined with an electrostatic filter. The HME is a foam which contains a salt (Calcium Chloride) The HME retains the heat and moisture of the exhaled air. When inhaling, the retained heat and moisture in the HME is given back to the lungs. HME use may help improve the function of the lungs and reduce problems with e.g. coughing and mucus production. New users may experience slight discomfort in the beginning, related to increased breathing resistance. During the first weeks of use, mucous production may seem to increase. This is normal and means that the mucus is getting thinner and easier to cough up. After a few weeks of HME use, this should stabilize and coughing, and mucus production usually decreases. The Provox Micron HME lid can be pressed down to occlude the stoma in order to speak with a voice prosthesis. When the pressure is released, the lid automatically comes up and the airway passage opens. Provox Micron HME helps to filter inhaled air through consistent normal use. Thereby, small particles, e.g. bacteria, viruses, dust and pollen are restricted from passing through the device into the lungs

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Product Information

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Manufacturer:
Atos Medical AB
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SE-242 35 Hörby, Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The Provox Micron HME is a heat and moisture exchanger (HME) and air filtration device for patients breathing through a tracheostoma. Provox Micron HME partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing. Provox Micron HME is intended to be used with the attachment devices in the Provox HME System.

Use specifications:

Intended medical indication
Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population
Patients of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.
Not intended for patients with mechanical ventilation.
Not intended for patients with a low tidal volume.

Intended usage
Single use. Prescription only.

Intended part of the body/type of tissue applied to or interacted with
The device is a surface device with direct contact with intact skin and indirect contact with the airways.

Intended user profile
The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use
Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician or caregiver.

Operating principles

Provox Micron HME can easily be attached and removed from the Provox HME System attachment devices when needed. In order to get good protection, make sure that the seal is airtight by closing the Provox Micron HME and check for leakage.
In order to speak with a voice prosthesis, press down the lid. This will direct the exhaled air through the voice prosthesis. When the pressure is released the airflow will pass through Provox Micron HME again. Provox Micron HME can be removed during or after coughing if the stoma needs to be cleaned from mucus.

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Contraindications:	This device shall not be used by patients who are unable to handle or remove the device themselves when needed, unless the patient is under constant supervision of a clinician or a trained caregiver. For example: patients who are unable to move their arms, patients with decreased levels of consciousness, or patients with diseases that put them at a risk for unpredictable periodic loss of consciousness.
CE Mark:	Yes. Devices are CE-marked
GMDN code:	58705 (Tracheostoma protective filter)
Sterilization:	Non-sterile
Raw material:	Lid: Thermoplastic elastomer (TPE) with beige polyethylene (PE) masterbatch (direct contact with the patient) Filter: Acrylic, Polypropylene (PP) (indirect contact with the patient) Cassette house: Polypropylene (PP) (direct contact with the patient) Cassette foam: Polyurethane and calcium chloride dihydrate (indirect contact with the patient)
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2 °C – 42 °C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None
Expiration date:	3 years after manufacturing.
Packaging:	Micron HME is single packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0002-XF

REF	Name	UDI-DI
7247	Provox Micron HME (5 pcs)	7331791001550
7248	Provox Micron HME (30 pcs)	7331791001567

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox XtraBase	7331791-ADH-0-000-0000-CQ
Provox StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox HME Cassette Adaptor	7331791-HME-A-000-0003-F5

Document Approvals
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