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This document has been electronically signed by the persons above.

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Product Information

Provox® XtraHME

Product description:

The Provox XtraHME Cassettes are part of the Provox HME System, which consists of HME Cassettes and Attachment Devices.
The Provox XtraHME Cassette is a single use device that features calcium chloride treated foam sponge in a plastic housing. This housing has a top lid that can be pushed down with a finger during speech to close the Cassette airtight. After releasing the finger, the top lid will get back automatically to its rest position (spring mechanism).
The Provox XtraHME Cassettes are available in two versions: The XtraMoist HME Cassette, which should be worn day and night under normal physical effort and the XtraFlow HME Cassette with a lower breathing resistance intended for use during physical activities. The latter can also be used in a two-step approach in order to get adapted to a more normal breathing resistance

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Product Information

Document ID: PF059-01-TechInfo **Edition:** 10

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

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

Intended Use: The Provox XtraHME Cassette is a single use, specialized device intended for patients breathing through a tracheostoma. It is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moist from exhaled air in the device. It partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

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. Over the counter.
Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin and mucosal membrane and as external communicating device the contact mode with tissue is indirect via air.
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.

Contraindications: The devices should only be used in accordance with the Instructions for Use. Patients without the physical, cognitive, or mental ability required to attach, remove or operate the devices themselves, should not use the devices independently and should only use them if they are under sufficient supervision of a clinician or a trained caregiver. The devices should not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non sterile

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Product Information

Raw material:	Housing: Polypropylene (PP) Lid: Polypropylene (PP) with beige polyethylene (PE) masterbatch Foam: Polyurethane (PUR) with calcium chloride ($CaCl_2$)
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:	**Provox XtraFlow HME** 20pcs/30pcs (10pcs/bag) are packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box. **Provox XtraMoist HME** 20pcs/30pcs (10pcs/bag) are packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box. **Provox XtraFlow & XtraMoist HME** 5+5pcs (5pcs/bag) are packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.

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Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0000-X9

REF	Name	UDI-DI
7272	Provox XtraFlow HME (20 pcs)	07331791009181
7273	Provox XtraMoist HME (20 pcs)	07331791009198
7290	Provox XtraMoist HME (30 pcs)	07331791005893
7290ES	Provox XtraMoist HME	07331791009204
7291	Provox XtraFlow HME (30 pcs)	07331791005909
7291ES	Provox XtraFlow HME	07331791009211
8229	Provox XtraFlow & XtraMoist HME (5+5pcs)	07331791010286

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