Product Information

Provox Life HME

Product description:

Provox Life HMEs are single-use devices for pulmonary rehabilitation. They come in different levels of humidification, breathing resistance and filtration that makes them suitable for different situations.
The different Provox Life HMEs are:
Home: when taking it easy, **Go:** when you are out and about, **Energy:** when physically active, **Protect:** when you need protection from bacteria, virus, dust and pollen, **Night:** when sleeping.

Product Information

Document ID:	PF086-01-TechInfo	**Edition:**	3.0

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

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

Intended Use: Provox Life HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma

Use specifications:

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

Intended patient population
Male and female 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 product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is Indirect via inhaled 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
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.

Contraindications: The device shall not be used by patients with reduced mental or physical cognitive ability. Patients who are unable to attach or remove the device themselves, or without sufficient knowledge how to use the device, or the cognitive ability to understand the risks connected to the use, should not use the device.
The device shall not be used by patients with a low tidal volume, as the added dead space may cause CO_2 (Carbon dioxide) retention.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material: Housing & Lid: Polypropylene (PP) with polyethylene (PE) master batch

Housing (only 8262 and no Lid): Polydimethylsiloxane (Silicone)

Product Information

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:	8310, 8311, 8312, 8262: The HMEs are single packed 10 pieces in a LD-Polyethylene blister sealed with a high barrier polyester-based lidding film. 3 blisters (total of 30 HMEs) are then packed together with an IFU in a cardboard box. 8313: The HMEs are single packed 5 pieces in a LD-Polyethylene blister sealed with a high barrier polyester-based lidding film. 3 blister (total of 15 HMEs) are then packed together with an IFU in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0001-XC

REF	Name	UDI-DI
8310	Provox Life Go HME	07331791011399
8311	Provox Life Home HME	07331791011405
8312	Provox Life Energy HME	07331791013744
8313	Provox Life Protect HME	07331791013751
8262	Provox Life Night HME	07331791014512

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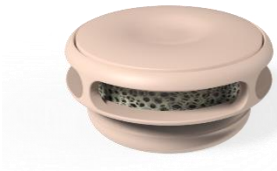
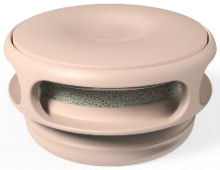
  </td><td>Home
  </td></tr>
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  </td><td>Protect
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<tr><td>Night
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Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life Adhesive	7331791-ADH-0-000-0001-CT
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P

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Document Approvals
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