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This document has been electronically signed by the persons above.

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Product Information

Provox® Luna HME

Product description:

The Provox Luna HME is a single use device that features calcium chloride treated foam sponge assembled into a silicone housing. By two finger occlusion seal for speech is obtained. The HME should be connected to Provox Luna Adhesive.

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Product Information

Document ID: PF077-01-TechInfo **Edition:** 06

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

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

Intended Use: The Provox Luna HME is a single use heat- and moisture exchanger, attachable to the Provox Luna Adhesive, for night-time use after total laryngectomy.

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:
Environment: Home use (normal daily environment without any hygienic 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 product shall not be used by patients with a decreased level of consciousness, patients with reduced mobility of the arms and/or hands, or patients who are unable to remove the device themselves.

The product shall 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

Sterilization: Non-sterile

Raw material: Housing: Polydimethylsiloxane (Silicone)
Foam: Polyurethane (PUR) with calcium chloride (CaCl2)

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:	5 Cassettes are packed in a plastic bag made of polyethylene and then six bags (total of 30 pcs) are packed together with instructions for use in a cardboard box.

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

REF	Name	UDI-DI
8013	Provox Luna HME (30 pcs)	07331791009242
8013-18	Provox Luna HME (30 pcs)	07331791012389

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ