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This document has been electronically signed by the persons above.

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Product Information

Provox® Luna Set

Product description:

Provox Luna HME:
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.

Provox Luna Adhesive:
Provox Luna Adhesive consists of an adhesive base, a peel-off liner and a soft connector for Provox Luna HME. Provox Luna Adhesive base is a skin-friendly hydrogel adhesive intended for night-time comfort and skin rest.

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Product Information

Document ID:	PF077-03-TechInfo	**Edition:**	03
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		

Intended Use: The Provox Luna Set is a combination of Provox Luna HME and Provox Luna Adhesive.

Provox Luna HME:
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.

Provox Luna Adhesive:
The Provox Luna Adhesive is a skin friendly, single use adhesive that provides attachment for the Provox Luna HME for night time use after total laryngectomy.

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Product Information

Use specifications:

Provox Luna HME:
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 device.

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.

Provox Luna Adhesive:
Intended medical indication: Facilitation of pulmonary rehabilitation after total laryngectomy.

Intended patient population: Any age and condition. The majority of the users are elderly.

Intended usage: Single use, over-the-counter device.

Intended part of the body/type of tissue applied to or interacted with: The device is a peristomal adhesive with skin contact.

Intended user profile: Patient, clinician, trained nurse, caregiver. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.

Intended conditions of use: The device will be used in hospitals, clinics and (mainly) in the patient´s normal environment. Daily usage with replacement as needed. The device can be used in any location and situation.

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Product Information

Contraindications:

Provox Luna HME:
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.

Provox Luna Adhesive:
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.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material:

Provox Luna HME:
Housing: Polydimethylsiloxane (Silicone)
Foam: Polyurethane (PUR) with calcium chloride ($CaCl_2$)

Provox Luna Adhesive:
Adapter: TPE
Carrier: Polyurethane film
Adhesive: Hydrogel, siliconized PET liner

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 - 30°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 packed in a LDPE plastic bag, 3 adhesives packed in aluminum bags, 1 instructions for use, packed in a cardboard box.

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Product Information

Devices under Basic UDI-DI: 7331791-KIT-0-000-0002-HS

REF	Name	UDI-DI
8025	Provox Luna Set	07331791010699
8025-18	Provox Luna Set	07331791012396

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH
Provox Luna ShowerAid	7331791-ADH-A-000-0000-U8

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