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This document has been electronically signed by the persons above.

Product Information

Provox® Luna™ Adhesive

**Product description:**

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.

Product Information

Document ID:	PF077-02-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 Adhesive is a skin friendly, single use adhesive that provides attachment for the Provox Luna HME for night time use after total laryngectomy.		
Use specifications:	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.		
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.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62175 (Stomal appliance skin-adherent patch)		
Sterilization:	None-sterile		
Raw material:	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.		

Product Information

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:

Each adhesive is packed in an aluminum bag and then packed together with an IFU in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-ADH-0-000-0000-CQ

REF	Name	UDI-DI
8014	Provox Luna Adhesive	07331791009259
8014-18	Provox Luna Adhesive	07331791014741

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Luna HME	7331791-HME-0-000-0000-X9
Provox Luna ShowerAid	7331791-ADH-A-000-0000-U8
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH