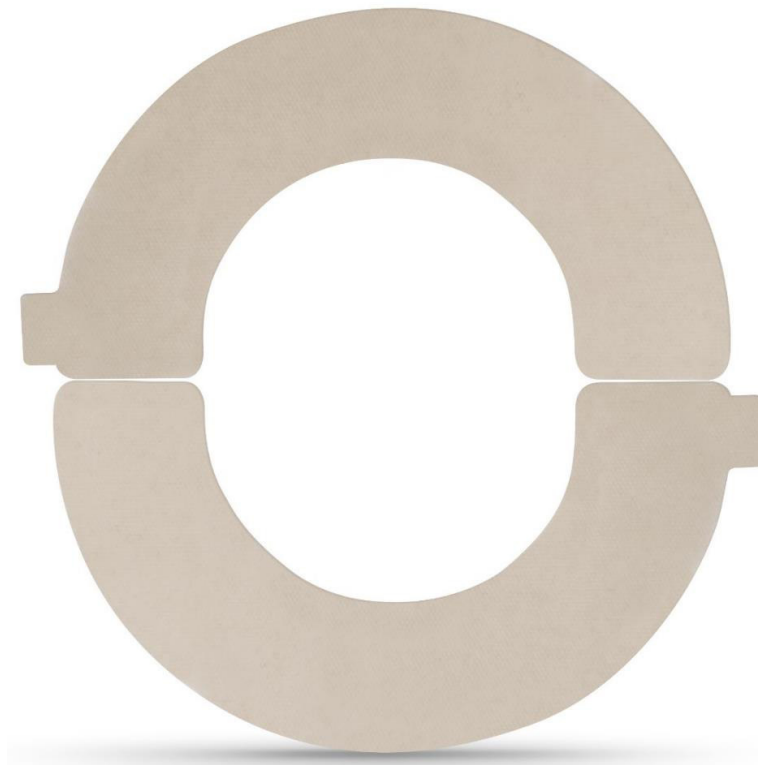


Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Abdallah Almashharawi - ABDALM	2022-03-24 - 14:58
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-03-24 - 15:33
Approved:	DD	Diana Tieger - DIATIE	2022-03-28 - 14:54
Released:	QA	Abdallah Almashharawi - ABDALM	2022-08-24 - 10:49

This document has been electronically signed by the persons above.

Product Information

Provox® Adhesive Strip

**Product description:**

The Provox Adhesive Strip is developed to be used as a seal for the Provox adhesives, e.g. during showering or when leakage from the adhesive develops.

Product Information

Document ID:	PF080-01-TechInfo	Edition:	05
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	Provox Adhesive Strip is a single use device to seal Provax adhesives, e.g. during showering.		
Use specifications:	Intended medical indication: Laryngectomized patients. Intended patient population: Gender: Male and female. Age: Typical average age for a laryngectomy is ~65 years. Intended usage: Single use. Intended part of the body/type of tissue applied to or interacted with: Intact skin. Intended user profile: Patient, clinician or other caregiver. Intended conditions of use: Normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.		
Contraindications:	There are no contraindications for the device.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62175 (Stomal appliance skin-adherent patch)		
Sterilization:	Non-sterile.		
Raw material:	Adhesive: Hydrocolloid, Polyethylene (PE) Liner: Super calendered glassine paper with siliconized surface Liner finger lift: Polyethylene (PE)		
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:	10 Provax Adhesive Strip in a plastic blister made of A-PET and PP will be packed in one paper box.		

Product Information

Devices under Basic UDI-DI: 7331791-ADH-A-000-0002-UE

REF	Name	UDI-DI
8015	Provox Adhesive Strip	07331791009525
8015-18	Provox Adhesive Strip	07331791014819

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 Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Adhesive Remover	7331791-ADH-A-000-0005-UP
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH
Provox StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox Life Standard	7331791-ADH-0-000-0001-CT
Provox Life Sensitive	7331791-ADH-0-000-0001-CT
Provox Life Stability	7331791-ADH-0-000-0001-CT
Provox Life Night Adhesive	7331791-ADH-0-000-0001-CT
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ
Provox Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ
Provox Silicone Glue	7331791-GEN-A-000-0003-EF