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Released:	QA	Elin Andersson - ELIAND	2021-11-09 - 10:09

This document has been electronically signed by the persons above.

Product Information

Provox® StabiliBase™ OptiDerm™



Product description:

The Provox StabiliBase OptiDerm is a peristomal adhesive that is designed to ensure an airtight attachment for the Provox HME system components. It consists of an adhesive part, a three part peel-off liner and an adapter where components of the HME system can be connected.

Product Information

Document ID:	PF071-01-TechInfo	Edition:	06
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	Provox StabiliBase OptiDerm adhesive is a single use device intended for laryngectomized patients breathing through a tracheostoma. The device is attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.		
Use specifications:	<p>Intended medical indication Product for rehabilitation for patients breathing through a tracheostoma.</p> <p>Intended patient population Intended for laryngectomized patients of any age breathing through a tracheostoma.</p> <p>Intended usage The device is attached to the skin around the tracheostoma in order to provide connections for components of the Provox HME system.</p> <p>Intended part of the body/type of tissue applied to or interacted with: The device is attached to the skin around the tracheostoma.</p> <p>Intended user profile Gender: Female and male Cognitive ability: By a clinician judged as sufficient Manual dexterity: By a clinician judged as sufficient. If not, the operating principle may be performed by someone else than the patient.</p> <p>Intended conditions of use Environment: Primarily home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Secondarily outpatient clinic use. Not intended for use during radiotherapy. Frequency of use: Continuous use. Replacement rate: Daily usage with replacement as needed.</p>		
Contraindications:	None		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	62175 (Stomal appliance skin-adherent patch)		
Sterilization:	Non-Sterile		
Raw material:	Adhesive: Hydrocolloid, Polyethylene (PE) Liner: Polypropylene (PP), siliconized Adapter: Ethylene-Butylacrylate (EBA)		
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.		



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:

The adhesives are separately packed in a plastic bag and with 15 or 3 adhesives in each box. Each box contains Instructions For Use (IFU).

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Product Information

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

REF	Name	UDI-DI
7318	Provox StabiliBase OptiDerm (15pc)	07331791009037
7328	Provox StabiliBase OptiDerm (3pcs)	07331791009044

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Xtra HME	7331791-HME-0-000-0000-X9
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Micron HME	7331791-HME-0-000-0002-XF
Provox FreeHands HME	7331791-HME-0-000-0003-XJ
Provox LaryTube	7331791-LTU-0-000-0004-3L
Provox Adhesive Remover	7331791-ADH-A-000-0005-UP
Provox Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH
Provox Shower Aid	7331791-ADH-A-000-0000-U8
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
Provox BasePlate Adaptor	7331791-HME-A-000-0003-F5