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This document has been electronically signed by the persons above.

Approved

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Product Information

Provox® StabiliBase



Product description:

Provox StabiliBase is designed to ensure an airtight attachment for the Provox HME system components. The Provox StabiliBase consists of an adhesive tape with a peel-off liner and a plastic adapter where components of the HME system can be connected. The firm base with vertical stabilizing bars provides support to the tracheostoma during speech. The design of the StabiliBase adapter can be especially suitable for deep tracheostomas. The peel-off liner is divided into three sections to facilitate application to the skin.

Product Information

Document ID:	PF066-01-TechInfo	Edition:	07
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	[The Provox StabiliBase 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:	Intended medical indication: Product for rehabilitation for patients breathing through a tracheostoma. Intended patient population: Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. Intended usage: Single use. Over-the-counter. Intended part of the body/type of tissue applied to or interacted with: The device is attached to the skin around the tracheostoma. 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: 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: Approximately every 1-4 days (May stay on as long as it provides an airtight seal). Replacement is performed by the patient, clinician or caregiver.		
Contraindications:	None		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62175 (Stomal appliance skin-adherent patch)		
Sterilization:	Non sterile		
Raw material:	Polyethylene (PE), Ethylene-butylacrylate (EBA), Siliconized Polypropylene (PP), Acrylic adhesive		
Latex information:	Not manufactured with natural rubber latex		

Product Information

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:	7289,7289-18: 15 adhesives are separately packed in a plastic bag of Ecobar. The products and instructions for use are packed in a cardboard box. 7299: 3 adhesives are separately packed in a plastic bag of Ecobar. The products and instructions for use are packed in a cardboard box.

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

REF	Name	UDI-DI
7289	Provox StabiliBase (15 pcs)	07331791008016
7289-18	Provox StabiliBase(15pcs)	07331791014680
7299	Provox StabiliBase (3 pcs)	07331791008023

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox XtraFlow HME	7331791-HME-0-000-0000-X9
Provox XtraMoist HME	7331791-HME-0-000-0000-X9
Provox ShowerAid	7331791-ADH-A-000-0000-U8
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Adhesive Remover	7331791-ADH-A-000-0005-UP
Provox Skin Barrier	7331791-ADH-A-000-0004-UL
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
Provox Micron HME	7331791-HME-0-000-0002-XF
Provox BasePlate Adaptor	7331791-HME-A-000-0003-F5
Provox Cleaning Towel	7331791-ADH-A-000-0003-UH
Provox Lary Tube with Ring	7331791-LTU-0-000-0002-3E
Provox FreeHands HME Cassette	7331791-HME-0-000-0003-XJ