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## Product Information

### Product® Group



#### Product description:

Provox Silicone Glue is a liquid glue used for increased adhesion of the Provox Adhesive. The glue cures via air contact. Long-term use may cause skin irritation.

## Product Information

<b>Document ID:</b>	PF013-01-TechInfo	<b>Edition:</b>	12
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	To reinforce attachment of Provox Adhesive base plates to intact skin around the tracheostoma.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	58978 (Synthetic-polymer liquid barrier dressing, nonsterile)		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Silicone in solvent. MSDS: DOW CORNING™ MG-2401 Silicone Adhesive		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	2 years after manufacturing.		
<b>Packaging:</b>	The glue is bottled in a glass bottle. The bottle is packed in a cardboard box.		

## Product Information

Devices under Basic UDI-DI: 7331791-GEN-A-000-0003-EF

REF	Name	UDI-DI
7720	Provox Silicone Glue	07331791002984
7720-18	Provox Silicone Glue	07331791014789

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 Adhesive Strip	7331791-ADH-A-000-0002-UE
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 Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ

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Released:	DD	Pontus Eklund - X-PONEKL	2020-10-28 - 16:36

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## Product Information

### Provox® BasePlate Adaptor



**Product description:**

The Provox BasePlate Adaptor ("adaptor") is an accessory product for rehabilitation after total laryngectomy. It allows attaching medical devices, (HME), with ISO 15mm standard connector to a tracheostoma by fitting it into a Provox Adhesive base plate, Provox LaryButton or Provox LaryTube. A typical example would be to attach an HME with built-in oxygen adaptor (TrachPhone). For single patient use.

Provox BasePlate Adaptor facilitates the use of TrachPhone together with Provox Adhesives or Provox LaryTube.

# Product Information

<b>Document ID:</b>	PF018-01-TechInfo	<b>Edition:</b>	08
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I (1.1 Rule 1)		
<b>Intended Use:</b>	The Provox BasePlate Adaptor ("adaptor") is an accessory product for rehabilitation after total laryngectomy. It allows attaching medical devices, (HME), with ISO 15mm standard connector to a tracheostoma by fitting it into a Provox Adhesive base plate, Provox LaryButton or Provox LaryTube. A typical example would be to attach an HME with built-in oxygen adapter (TrachPhone). For single patient use.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	58705 (Tracheostoma protective filter)		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Polyether ether ketone (PEEK)		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	5 years after manufacturing.		
<b>Packaging:</b>	BasePlate Adaptor is separately packed in a plastic bag and together with instructions for use in a cardboard box.		

## Product Information

**Devices under Basic UDI-DI:** 7331791-HME-A-000-0003-F5

REF	Name	UDI-DI
7263	Provox BasePlate Adaptor	7331791001697

**Atos Medical AB Compatible products:**

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox StabiliBase Provox XtraBase Provox StabiliBase OptiDerm Provox Flexiderm Provox Optiderm	7331791-ADH-0-000-0000-CQ
TrachPhone	7331791-HME-0-000-0006-XT
Freevent DualCare	7331791-HME-0-000-0005-XQ
Freevent XtraCare	7331791-HME-0-000-0004-XM



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Approved:	DD	Jon Berg - JONBER	2021-11-08 - 15:35
Released:	QA	Alexandra Holmberg - ALEHOL	2021-11-11 - 11:20

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# Product Information

## Provox® ShowerAid

**Product description:**

Shower protection device. Use together with Provox appliance holders.

## Product Information

<b>Document ID:</b>	PF020-01-TechInfo	<b>Edition:</b>	11
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	The Provox ShowerAid is used to temporarily replace the Provox XtraMoist/Provox XtraFlow/Provox FreeHands/Provox FreeHands FlexiVoice/Provox Micron HME during showering. The device is for single patient use.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	62047 (Tracheostoma shower shield)		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Polypropylene (PP) with blue masterbatch.		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	The Shower Aid is packed in a plastic bag that is packed together with instructions for use in a cardboard box also including one piece of Provox FlexiDerm Oval.		

# Product Information

**Devices under Basic UDI-DI:** 7331791-ADH-A-000-0000-U8

REF	Name	UDI-DI
7260	Provox ShowerAid	7331791001680
7260-18	Provox ShowerAid	7331791014796

**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 StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Strip	7331791-ADH-A-000-0002-UE
Provox Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38

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## Provox® Adhesives



### Product description:

Provox Adhesives are designed to ensure an airtight attachment for the Provox HME system components. The adhesives have an adhesive part, a peel-off liner and an adapter where components of the HME system can be connected.

**FlexiDerm** is a very flexible material and has the strongest adhesive properties. It is a sticky, yet soft and flexible adhesive. The FlexiDerm adhesives are Provox FlexiDerm Round/Oval/Plus and Provox **XtraBase** with a concave shaped base.

The hydrocolloid **OptiDerm** is made of a hypoallergenic adhesive material that forms a gel in contact with water. The OptiDerm adhesives are Provox OptiDerm Round/Oval/Plus.

## Product Information

<b>Document ID:</b>	PF025-01-TechInfo	<b>Edition:</b>	11
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	The Provox Adhesives are single use devices intended for laryngectomized patients breathing through a tracheostoma. The devices are attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.		
<b>Contraindications:</b>	None.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	62175 (Stomal appliance skin-adherent patch)		
<b>Sterilization:</b>	Non sterile		
<b>Raw material:</b>	FlexiDerm: Ethylene-butyl acrylate (EBA), Polyethylene (PE), Acrylic adhesive. XtraBase: Ethylene-butyl acrylate (EBA), Polyethylene (PE), Acrylic adhesive. OptiDerm: Ethylene-butyl acrylate (EBA), Hydrocolloid, Polyethylene (PE), Acrylic adhesive.		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	The adhesives are separately packed in a plastic bag and then in a cardboard box together with instructions for use.		

## Product Information

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

REF	Name	UDI-DI
7253	Provox Adhesive FlexiDerm Round	07331791001611
7254	Provox Adhesive FlexiDerm Oval	07331791001628
7255	Provox Adhesive OptiDerm Round	07331791001635
7256	Provox Adhesive OptiDerm Oval	07331791001642
7253ES	Provox Adhesive FlexiDerm Round	07331791011351
7254ES	Provox Adhesive FlexiDerm Oval	07331791011368
7254JP	Provox Adhesive FlexiDerm Oval (15pcs)	07331791015328
7256JP	Provox Adhesive OptiDerm Oval (15pcs)	07331791015335
7331	Provox Adhesive FlexiDerm Plus	07331791008160
7332	Provox Adhesive OptiDerm Plus	07331791008177
8234	Provox FlexiDerm Round (3pcs)	07331791010309
8235	Provox FlexiDerm Oval (3pcs)	07331791010316
8236	Provox OptiDerm Round (3pcs)	07331791010323
8237	Provox OptiDerm Oval (3pcs)	07331791010330
8238	Provox FlexiDerm Plus (3pcs)	07331791010347
8239	Provox OptiDerm Plus (3pcs)	07331791010354
7253-18	Provox Adhesive FlexiDerm Round	07331791014574
7254-18	Provox Adhesive FlexiDerm Oval	07331791014581
7255-18	Provox Adhesive OptiDerm Round	07331791014628
7256-18	Provox Adhesive OptiDerm Oval	07331791014635
7331-18	Provox Adhesive FlexiDerm Plus	07331791014567
7332-18	Provox Adhesive OptiDerm Plus	07331791014642
8234-18	Provox FlexiDerm Round (3pcs)	07331791014598
8235-18	Provox FlexiDerm Oval (3pcs)	07331791014604
8236-18	Provox OptiDerm Round (3pcs)	07331791014659
8237-18	Provox OptiDerm Oval (3pcs)	07331791014666
8238-18	Provox FlexiDerm Plus (3pcs)	07331791014611
8239-18	Provox OptiDerm Plus (3pcs)	07331791014673
7265	Provox XtraBase Adhesive	07331791001703
7265JP	Provox XtraBase Adhesive (15pcs)	07331791015359
8233	Provox XtraBase (3pcs)	07331791010293
7265-18	Provox XtraBase Adhesive	07331791014727
8233-18	Provox XtraBase (3pcs)	07331791014734

### 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



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**Provox® HME Cassette Adaptor****Product description:**

The Provox HME Cassette Adaptor is intended to facilitate a connection between Provox HME Cassette and on the market available tracheal cannulas with ISO-cone (15mm).

For laryngectomies who need a cannula initially or for a longer period of time. Enables immediate start of pulmonary rehabilitation with HME.

## Product Information

<b>Document ID:</b>	PF038-01-TechInfo	<b>Edition:</b>	10
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I (1.1 Rule 1)		
<b>Intended Use:</b>	The Provox HME Cassette Adaptor is intended to facilitate a connection between Provox HME Cassettes and on the market available tracheal cannulas with ISO-cone (15mm).		
<b>Use specifications:</b>	<p><i>Intended medical indication:</i> For patients breathing through a tracheostoma who use a device with a 15 mm connector. To enable the use of a different diameter HME for pulmonary rehabilitation.</p> <p><i>Intended patient population:</i> Male and female patients breathing through a tracheostoma. 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><i>Intended usage:</i> Used together with an HME. Intended for attachment on cannulas with 15 mm ISO connection. Continuous use. Intended part of the body/type of tissue applied to or interacted with: Indirect contact with tissue/bone/dentin via inhaled air.</p> <p><i>Intended user profile:</i> Patient (continuous use and replacement), clinician, trained nurse (primary fitting).</p> <p><i>Intended conditions of use:</i> Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Hospital use. Frequency of use: Continuous use. Replacement rate: Replaced after maximum usage for 6 months or sooner if damaged.</p>		
<b>Contraindications:</b>	N/A		
<b>CE Mark:</b>	Yes. Device is CE-marked.		
<b>GMDN code:</b>	63623 (Tracheostomy tube adaptor)		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Silicone		
<b>Latex information:</b>	Not manufactured with natural rubber latex		

## Product Information

<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
<b>Waste handling and disposal:</b>	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.
<b>Hazardous components:</b>	None
<b>Expiration date:</b>	5 years after manufacturing.
<b>Packaging:</b>	1 Cassette Adaptor in a plastic bag. 1 IFU

**Devices under Basic UDI-DI: 7331791-HME-A-000-0003-F5**

REF	Name	UDI-DI
7246	Provox HME Cassette Adaptor	7331791001543

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox Xtra HME	7331791-HME-0-000-0000-X9
Provox Micron HME	7331791-HME-0-000-0002-XF
Provox FreeHands HME	7331791-HME-0-000-0003-XJ
Provox ShowerAid	7331791-ADH-A-000-0000-U8

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Released:	QA	Peter Sundsten - X-PETSUN	2020-05-18 - 11:37

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## Product Information

### Provox® StabiliBase



#### Product description:

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

<b>Document ID:</b>	PF066-01-TechInfo	<b>Edition:</b>	06
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	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.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	62175 (Stomal appliance skin-adherent patch)		
<b>Sterilization:</b>	Non sterile		
<b>Raw material:</b>	Polyethylene (PE), Ethylene-butylacrylate (EBA), Siliconized Polypropylene (PP), Acrylic adhesive		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	Each StabiliBase adhesive is packed in a sealed plastic pouch. 7289, 7289-18 contains 15 adhesives and 1 IFU packed in a cardboard box. 7299, 7299-18 contains 3 adhesive and 1 IFU packed in a cardboard box.		

## Product Information

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

REF	Name	UDI-DI
7289	Provox StabiliBase (15 pcs)	07331791008016
7299	Provox StabiliBase (3 pcs)	07331791008023
7289-18	Provox StabiliBase(15pcs)	07331791014680
7299-18	Provox StabiliBase(3pcs)	07331791014697

**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



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## 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

<b>Document ID:</b>	PF071-01-TechInfo	<b>Edition:</b>	06
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	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.		
<b>Use specifications:</b>	<p><b>Intended medical indication</b> Product for rehabilitation for patients breathing through a tracheostoma.</p> <p><b>Intended patient population</b> Intended for laryngectomized patients of any age breathing through a tracheostoma.</p> <p><b>Intended usage</b> The device is attached to the skin around the tracheostoma in order to provide connections for components of the Provox HME system.</p> <p><b>Intended part of the body/type of tissue applied to or interacted with:</b> The device is attached to the skin around the tracheostoma.</p> <p><b>Intended user profile</b> 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><b>Intended conditions of use</b> 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>		
<b>Contraindications:</b>	None		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	62175 (Stomal appliance skin-adherent patch)		
<b>Sterilization:</b>	Non-Sterile		
<b>Raw material:</b>	Adhesive: Hydrocolloid, Polyethylene (PE) Liner: Polypropylene (PP), siliconized Adapter: Ethylene-Butylacrylate (EBA)		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	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).*

Released

Document No: 10000043060 Edition: 06 Release date: 2021-11-09

## 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

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Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:10
Released:	QA	Peter Sundsten - X-PETSUN	2020-06-16 - 09:58

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# Product Information

## Provox® Skin Barrier



**Product description:**

Provox Skin Barrier contains a sting free solvent that is wiped on skin providing a barrier between Provox adhesive and the skin.

Document No: 10000038383 Edition: 04 Release date: 2020-06-16

Released

# Product Information

<b>Document ID:</b>	PF076-01-TechInfo	<b>Edition:</b>	04
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	Provox Skin Barrier is a single use wipe for laryngectomized patients that forms a barrier between Provox Adhesive and the skin.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	58978 (Synthetic-polymer liquid barrier dressing, non-sterile)		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Cloth: Polyester and Viscous fabric Solution: Hexamethyldisiloxane, Isopropyl-myristate and Trimethylsiloxysilicate.		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	Please read the instruction for use or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Atos Medical AB.		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	1 wipe in a bag and 50 bags in one box.		



## Product Information

**Devices under Basic UDI-DI:** 7331791-ADH-A-000-0001-UB

REF	Name	UDI-DI
8011	Provox Skin Barrier (50 pcs)	07331791009228
8011-18	Provox Skin Barrier	07331791014765

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox Adhesive Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Optiderm	7331791-ADH-0-000-0000-CQ
Provox XtraBase Adhesive	7331791-ADH-0-000-0000-CQ
Provox Adhesive Remover	7331791-ADH-A-000-0001-UB
Provox Cleaning Towel	7331791-ADH-A-000-0001-UB
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Life Standard Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Stability Adhesive	7331791-ADH-0-000-0001-CT

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Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:10
Released:	QA	Peter Sundsten - X-PETSUN	2020-06-16 - 09:57

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## Product Information

### Provox® Adhesive Remover



**Product description:**

Provox Adhesive Remover contains a sting free solvent that helps laryngectomized patients remove Provox Adhesives and Provox Silicone Glue.

## Product Information

<b>Document ID:</b>	PF076-02-TechInfo	<b>Edition:</b>	04
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule1		
<b>Intended Use:</b>	Provox Adhesive Remover is a single use wipe to help laryngectomized patients remove Provox Adhesives and Provox Silicone Glue.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	60494 (Medical adhesive remover, non-sterile)		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Cloth: Polyester and Viscous fabric Solution: Hexamethyldisiloxane, Isopropyl-myristate.		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	Please read the instruction for use or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Atos Medical AB.		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	1 wipe in a bag and 50 bags in one box.		

## Product Information

**Devices under Basic UDI-DI:** 7331791-ADH-A-000-0001-UB

REF	Name	UDI-DI
8012	Provox Adhesive Remover (50 pcs)	07331791009235
8012-18	Provox Adhesive Remover	07331791014772

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox Adhesive Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Optiderm	7331791-ADH-0-000-0000-CQ
Provox XtraBase Adhesive	7331791-ADH-0-000-0000-CQ
Provox Skin Barrier	7331791-ADH-A-000-0001-UB
Provox Cleaning Towel	7331791-ADH-A-000-0001-UB
Provox Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Life Standard Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Stability	7331791-ADH-0-000-0001-CT

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2021-12-06 - 09:59
Reviewed:	QA	Karolina Nilsson - KARNIL	2021-12-07 - 09:56
Approved:	DD	Diana Tieger - DIATIE	2021-12-07 - 10:35
Released:	QA	Carolina Johansson - SEHRBJNC	2021-12-27 - 14:37

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# Product Information

## Provox Cleaning Towel



**Product description:**

Provox Cleaning Towel is alcohol-based and non-perfumed and is available in resealable pouches.

## Product Information

<b>Document ID:</b>	PF076-03-TechInfo	<b>Edition:</b>	02
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	Provox Cleaning Towel is intended for cleaning around the stoma, it will remove oil from the skin. They are indented to use before application of Provox Adhesives.		
<b>Use specifications:</b>	N/A		
<b>Contraindications:</b>	N/A		
<b>CE Mark:</b>	Yes. Devices are CE-marked.		
<b>GMDN code:</b>	46205		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Towel: Spunlaced viscose, Polyester Solution: Chlorhexidine, Ethanol, BTC 2125, deionised water. MSDS-7244-SE		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	The product contains ethanol (concentrated ethanol is flammable) and chlorhexidine (concentrated chlorhexidine may cause eye damages if in contact with the eyes).		
<b>Expiration date:</b>	2 years after manufacturing.		
<b>Packaging:</b>	10 towels are packed together in a plastic bag made of polyester/polyethene and PT 12 (white)/PE 70. 20 plastic bags are packed together in every cardboard box		



## Product Information

**Devices under Basic UDI-DI:** 7331791-ADH-A-000-0003-UH

REF	Name	UDI-DI
7244*	Provox Cleaning Towel 10-p	07331791001536
7244**	Provox Cleaning Towel 10-p	07331791015762
7244-18	Provox Cleaning Towel	07331791014758

\*Contains 20 bags with 10 towels

\*\*Contains 1 bag with 10 towels

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox Adhesive Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Adhesive Optiderm	7331791-ADH-0-000-0000-CQ
Provox XtraBase Adhesive	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 Silicone Glue	7331791-GEN-A-000-0003-EF
Provox Life Standard Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesives	7331791-ADH-0-000-0001-CT
Provox Life Stability Adhesive	7331791-ADH-0-000-0001-CT
Provox Life Night Adhesive	7331791-ADH-0-000-0001-CT

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Issued:	QA	Peter Sundsten - X-PETSUN	2020-04-21 - 09:51
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Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:08
Released:	QA	Peter Sundsten - X-PETSUN	2020-05-25 - 10:39

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## Product Information

### Provox® Luna™ Adhesive



**Product description:**

Before the adhesive is attached to the skin the adhesive liner is removed.  
Provox Luna HME or Provox Luna ShowerAid can be attached to the adhesive.

Document No: 10000030311 Edition: 05 Release date: 2020-05-25

Released

## Product Information

<b>Document ID:</b>	PF077-02-TechInfo	<b>Edition:</b>	05
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	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.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	62175 (Stomal appliance skin-adherent patch)		
<b>Sterilization:</b>	Non-Sterile		
<b>Raw material:</b>	Adapter: TPE Carrier: Polyurethane film Adhesive: Hydrogel, siliconised PET liner		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 30°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	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

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Alexandra Holmberg - ALEHOL	2021-11-08 - 07:35
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Approved:	DD	Jon Berg - JONBER	2021-11-08 - 15:35
Released:	QA	Alexandra Holmberg - ALEHOL	2021-11-11 - 11:17

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# Product Information

## Provox® Luna ShowerAid



**Product description:**

The Provox Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma.

## Product Information

<b>Document ID:</b>	PF079-01-TechInfo	<b>Edition:</b>	05
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1.		
<b>Intended Use:</b>	The Provox Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma. Single patient use.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	62047		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Polypropylene (PP) with white masterbatch		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	The Provox Luna ShowerAid is packed in a plastic bag and then together with instructions for use in a cardboard box.		



# Product Information

**Devices under Basic UDI-DI:** 7331791-ADH-A-000-0000-U8

REF	Name	UDI-DI
8016	Provox Luna ShowerAid	07331791009532
8016-18	Provox Luna ShowerAid	07331791014802

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ
Provox Luna Set	7331791-KIT-0-000-0002-HS

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 14:55
Released:	DD	Pontus Eklund - X-PONEKL	2020-10-28 - 16:33

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## 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

<b>Document ID:</b>	PF080-01-TechInfo	<b>Edition:</b>	04
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule		
<b>Intended Use:</b>	Provox Adhesive Strip is a single use device to seal Provox adhesives, e.g. during showering.		
<b>CE Mark:</b>	Yes, the devices are CE marked.		
<b>GMDN code:</b>	62175		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Adhesive: Hydrocolloid, Polyethylene (PE) Liner: Super calendered glassine paper with siliconized surface Liner finger lift: Polyethylene (PE)		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	10 Provox Adhesive Strip in a blister 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 Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ