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Issued:	QA	Abdallah Almashharawi - ABDALM	2023-01-12 - 10:35
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Product Information

Provox® Micron HME

Product description:

Provox Micron HME is a Heat and Moisture Exchanger combined with an electrostatic filter. The HME is a foam which contains a salt (Calcium Chloride) The HME retains the heat and moisture of the exhaled air. When inhaling, the retained heat and moisture in the HME is given back to the lungs. HME use may help improve the function of the lungs and reduce problems with e.g. coughing and mucus production. New users may experience slight discomfort in the beginning, related to increased breathing resistance. During the first weeks of use, mucous production may seem to increase. This is normal and means that the mucus is getting thinner and easier to cough up. After a few weeks of HME use, this should stabilize and coughing, and mucus production usually decreases. The Provox Micron HME lid can be pressed down to occlude the stoma in order to speak with a voice prosthesis. When the pressure is released, the lid automatically comes up and the airway passage opens. Provox Micron HME helps to filter inhaled air through consistent normal use. Thereby, small particles, e.g. bacteria, viruses, dust and pollen are restricted from passing through the device into the lungs.

Document No: 10000043072 Edition: 09 Release date: 2023-04-28

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Document Number: VV-0544124 Status: Effective Version: 1.0
Name: PF054-01-TECHINFO

Product Information

Document ID:	PF054-01-TechInfo	**Edition:**	09

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The Provox Micron HME is a heat and moisture exchanger (HME) and air filtration device for patients breathing through a tracheostoma. Provox Micron HME partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing. Provox Micron HME is intended to be used with the attachment devices in the Provox HME System.

Use specifications:

Intended medical indication:
Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population:
Any age and condition. The majority of the users are elderly.

Intended usage:
Single use.

Intended part of the body/type of tissue applied to or interacted with:
The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is Indirect via inhaled air.

Intended user profile:
The product is supposed to be handled by patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use:
Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician or caregiver.

Contraindications: This device shall not be used by patients who are unable to handle or remove the device themselves when needed unless the patient is under constant supervision of a clinician or a trained caregiver. For example: patients who are unable to move their arms, patients with decreased levels of consciousness, or patients with diseases that put them at a risk for unpredictable periodic loss of consciousness.

CE Mark: Yes. Devices are CE-marked

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

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Product Information

Raw material: Lid: Thermoplastic elastomer (TPE) with beige polyethylene (PE) masterbatch
Filter: Acrylic, Polypropylene (PP)
Cassette house: Polypropylene (PP)
Cassette foam: Polyurethane and calcium chloride dihydrate

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: Micron HME is single packed in a plastic bag of polyethylene.
The products and instructions for use are packed in a cardboard box.

Devices under Basic UDI-DI: 7331791-HME-0-000-0002-XF

REF	Name	UDI-DI
7247	Provox Micron HME (5 pcs)	7331791001550
7248	Provox Micron HME (30 pcs)	7331791001567
7247-18	Provox Micron HME (5 pcs)	7331791013393
7248-18	Provox Micron HME (30 pcs)	7331791012341

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 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
Provox HME Cassette Adaptor	7331791-HME-A-000-0003-F5

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Issued:	QA	Carolina Johansson - SEHRBJNC	2022-06-13 - 08:07
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Approved:	DD	Diana Tieger - DIATIE	2022-06-15 - 15:20

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Product Information

Provox® XtraHME

Product description:

The Provox XtraHME Cassettes are part of the Provox HME System, which consists of HME Cassettes and Attachment Devices.
The Provox XtraHME Cassette is a single use device that features calcium chloride treated foam sponge in a plastic housing. This housing has a top lid that can be pushed down with a finger during speech to close the Cassette airtight. After releasing the finger, the top lid will get back automatically to its rest position (spring mechanism).
The Provox XtraHME Cassettes are available in two versions: The XtraMoist HME Cassette, which should be worn day and night under normal physical effort and the XtraFlow HME Cassette with a lower breathing resistance intended for use during physical activities. The latter can also be used in a two-step approach in order to get adapted to a more normal breathing resistance

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Document Number: VV-0544048 Status: Effective Version: 1.0
Name: PF059-01-Techinfo

Product Information

Document ID: PF059-01-TechInfo **Edition:** 10

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The Provox XtraHME Cassette is a single use, specialized device intended for patients breathing through a tracheostoma. It is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moist from exhaled air in the device. It partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

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.
Not intended for patients with mechanical ventilation.
Not intended for patients with a low tidal volume.
Intended usage:
Single use. Over the counter.
Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin and mucosal membrane and as external communicating device the contact mode with tissue is indirect via air.
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: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician or caregiver.

Contraindications: The devices should only be used in accordance with the Instructions for Use. Patients without the physical, cognitive, or mental ability required to attach, remove or operate the devices themselves, should not use the devices independently and should only use them if they are under sufficient supervision of a clinician or a trained caregiver. The devices should not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non sterile

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Product Information

Raw material:	Housing: Polypropylene (PP) Lid: Polypropylene (PP) with beige polyethylene (PE) masterbatch Foam: Polyurethane (PUR) with calcium chloride ($CaCl_2$)
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:	**Provox XtraFlow HME** 20pcs/30pcs (10pcs/bag) are packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box. **Provox XtraMoist HME** 20pcs/30pcs (10pcs/bag) are packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box. **Provox XtraFlow & XtraMoist HME** 5+5pcs (5pcs/bag) are packed in a plastic bag of polyethylene. The products and instructions for use are packed in a cardboard box.

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Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0000-X9

REF	Name	UDI-DI
7272	Provox XtraFlow HME (20 pcs)	07331791009181
7273	Provox XtraMoist HME (20 pcs)	07331791009198
7290	Provox XtraMoist HME (30 pcs)	07331791005893
7290ES	Provox XtraMoist HME	07331791009204
7291	Provox XtraFlow HME (30 pcs)	07331791005909
7291ES	Provox XtraFlow HME	07331791009211
8229	Provox XtraFlow & XtraMoist HME (5+5pcs)	07331791010286

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 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
Provox HME Cassette Adaptor	7331791-HME-A-000-0003-F5

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Released:	QA	Abdallah Almashharawi - ABDALM	2022-10-21 - 08:53

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Product Information

Provox® Coming Home®

Document No: 10000031395 Edition: 24 Release date: 2022-10-21

Released

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Product Information

Product description:

Provox Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home. Content in the Coming Home package:

8224DE, 8224CA
- 10 pcs Provox FlexiDerm Oval
- 5 pcs Provox OptiDerm Oval
- 3 pcs Provox StabiliBase
- 7 pcs Provox Luna Adhesive
- 10 pcs Provox Luna HME
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron *
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Provox Luna ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

*8224DE does not include Micron

8224FR, 8224ES, 8224EM
- 10 pcs Provox FlexiDerm Oval
- 15 pcs Provox OptiDerm Oval
- 3 pcs Provox StabiliBase
- 20 pcs Provox XtraMoist HME
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224PL
- 14 pcs Provox FlexiDerm Oval
- 15 pcs Provox OptiDerm Oval
- 3 pcs Provox StabiliBase
- 20 pcs Provox XtraFlow HME
- 20 pcs Provox XtraMoist HME
- 1 pc Provox Micron
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224PT
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

8224JP
- 9 pcs Provox FlexiDerm Oval
- 15 pcs Provox OptiDerm Oval
- 20 pcs Provox XtraMoist HME
- 20 pcs Provox XtraFlow HME
- 1 pc Provox Micron
- 9 pcs Skin Barrier
- 9 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox ShowerAid
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

Document No: 10000031395 Edition: 24 Release date: 2022-10-21

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Product Information

Provox® Life™ Coming Home®

Product description:

Provox Life Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home.
Content in the Life Coming Home package:

8224DK, 8224FI, 8224NL, 8224US21, 8224SE, 8224IT, 8224DERW, 8224FRRW, 8224ENRW, 8224NO, 8224HU

- 10 pcs Provox Life Standard Adhesive Oval
- 10 pcs Provox Life Sensitive Adhesive Oval
- 10 pcs Provox Life Night Adhesive
- 3 pcs Provox Life Stability Adhesive
- 10 pcs Provox Life Go HME
- 10 pcs Provox Life Home HME
- 10 pcs Provox Life Night HME
- 2 pcs Provox Life Protect HME
- 10 pcs Skin Barrier
- 10 pcs Adhesive Remover
- 1 pc Provox Cleaning Towel
- 1 pc Provox Life Shower
- 1 pc Pocket mirror
- 1 pc Pocket flashlight

Document No: 10000031395 Edition: 24 Release date: 2022-10-21

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Product Information

Document ID: PF075-01-TechInfo **Edition:** 24

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I (1.1 rule 1)

Intended Use: Provox Coming Home/Provox Life Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home.

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:
Multiple use. To be provided by clinician.

Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin and mucosal membrane and as external communicating device the contact mode with tissue is indirect via air.

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: Home use (normal daily environment without any specific environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician, or caregiver.

Contraindications: Not intended for patients with mechanical ventilation.
Not intended for patients with a low tidal volume.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material: The main fabric used in the bag is a polyester that fulfills the REACH regulations. Materials in included devices are not accounted for here.

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Product Information

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:	Temperature limit: 2-30 °C for 8224SE, 8224DK, 8224NO, 8224FI, 8224DE, 8224NL, 8224US21, 8224CA, 8224HU, 8224IT, 8224FR, 8224DERW, 8224FRRW, 8224ENRW. Temperature limit: 2-42 °C for 8224PL, 8224PT, 8224JP, 8224ES, 8224EM.
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:	The included device with the shortest shelf life upon packing of each lot, will determine the shelf life.
Packaging:	Provox Coming Home/Provox Life Coming is a textile bag and each bag is surrounded with a cardboard sleeve holding the label and symbols.

Document No: 10000031395 Edition: 24 Release date: 2022-10-21

Product Information

Devices under Basic UDI-DI: 7331791-KIT-0-000-0000-HL

REF	Name	UDI-DI
8224CA	Provox Coming Home Canada	7331791009594
8224FR	Provox Coming Home France	7331791009549
8224EM	Provox Coming Home Generic	7331791011108
8224DE	Provox Coming Home Germany	7331791009310
8224JP	Provox Coming Home Japan	7331791009471
8224PL	Provox Coming Home Poland	7331791011443
8224PT	Provox Coming Home Portugal	7331791009563
8224ES	Provox Coming Home Spain	7331791009556
8224DK	Provox Life Coming Home Denmark	7331791009440
8224NL	Provox Life Coming Home Dutch	7331791009327
8224ENRW	Provox Life Coming Home English	7331791015809
8224FI	Provox Life Coming Home Finland	7331791009464
8224FRRW	Provox Life Coming Home French	7331791015786
8224DERW	Provox Life Coming Home German	7331791015793
8224HU	Provox Life Coming Home Hungary	7331791016035
8224IT	Provox Life Coming Home Italian	7331791009570
8224NO	Provox Life Coming Home Norway	7331791009457
8224SE	Provox Life Coming Home Sweden	7331791009433
8224US21	Provox Life Coming Home USA	7331791015564

Atos Medical AB compatible products: N/A

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Approved:	DD	Diana Tieger - DIATIE	2022-03-23 - 13:26
Released:	QA	Abdallah Almashharawi - ABDALM	2022-08-24 - 10:48

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Product Information

Provox® Luna HME

Product description:

The Provox Luna HME is a single use device that features calcium chloride treated foam sponge assembled into a silicone housing. By two finger occlusion seal for speech is obtained. The HME should be connected to Provox Luna Adhesive.

Document No: 10000030281 Edition: 06 Release date: 2022-08-24

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Product Information

Document ID: PF077-01-TechInfo **Edition:** 06

Manufacturer: Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The Provox Luna HME is a single use heat- and moisture exchanger, attachable to the Provox Luna Adhesive, for night-time use after total laryngectomy.

Use specifications: **Intended medical indication:** Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population:
Male and female of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.
Not intended for patients with mechanical ventilation.
Not intended for patients with a low tidal volume.

Intended usage: Single use, Over-the-counter.

Intended part of the body/type of tissue applied to or interacted with: The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is Indirect via inhaled air.

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: Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician, or caregiver.

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.

The product shall not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705

Sterilization: Non-sterile

Raw material: Housing: Polydimethylsiloxane (Silicone)
Foam: Polyurethane (PUR) with calcium chloride (CaCl2)

Product Information

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:	5 Cassettes are packed in a plastic bag made of polyethylene and then six bags (total of 30 pcs) are packed together with instructions for use in a cardboard box.

Devices under Basic UDI-DI: 7331791-HME-0-000-0000-X9

REF	Name	UDI-DI
8013	Provox Luna HME (30 pcs)	07331791009242
8013-18	Provox Luna HME (30 pcs)	07331791012389

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Approved:	DD	Diana Tieger - DIATIE	2022-03-24 - 14:16
Released:	QA	Abdallah Almashharawi - ABDALM	2022-08-24 - 10:48

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Product Information

Provox® Luna Set

Product description:

Provox Luna HME:
The Provox Luna HME is a single use device that features calcium chloride treated foam sponge assembled into a silicone housing. By two finger occlusion seal for speech is obtained. The HME should be connected to Provox Luna Adhesive.

Provox Luna Adhesive:
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.

Document No: 10000030686 Edition: 03 Release date: 2022-08-24

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Product Information

Document ID:	PF077-03-TechInfo	**Edition:**	03
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		

Intended Use: The Provox Luna Set is a combination of Provox Luna HME and Provox Luna Adhesive.

Provox Luna HME:
The Provox Luna HME is a single use heat- and moisture exchanger, attachable to the Provox Luna Adhesive, for night-time use after total laryngectomy.

Provox Luna Adhesive:
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.

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Product Information

Use specifications:

Provox Luna HME:
Intended medical indication: Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population:
Male and female of any age.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.
Not intended for patients with mechanical ventilation.
Not intended for patients with a low tidal volume.

Intended usage: Single use, over-the-counter device.

Intended part of the body/type of tissue applied to or interacted with: The product is placed in front of the tracheostoma to condition respiratory air. The tissue contact is Indirect via inhaled air.

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: Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use.
Replacement rate: Max usage for 24 hours. Replacement is performed by the patient, clinician, or caregiver.

Provox Luna Adhesive:
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.

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Product Information

Contraindications:

Provox Luna HME:
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.
The product shall not be used by patients with a low tidal volume, as the added dead space may cause CO2 (Carbon dioxide) retention.

Provox Luna Adhesive:
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: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material:

Provox Luna HME:
Housing: Polydimethylsiloxane (Silicone)
Foam: Polyurethane (PUR) with calcium chloride ($CaCl_2$)

Provox Luna Adhesive:
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.

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: 5 cassettes packed in a LDPE plastic bag, 3 adhesives packed in aluminum bags, 1 instructions for use, packed in a cardboard box.

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Product Information

Devices under Basic UDI-DI: 7331791-KIT-0-000-0002-HS

REF	Name	UDI-DI
8025	Provox Luna Set	07331791010699
8025-18	Provox Luna Set	07331791012396

Atos Medical AB compatible products:

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

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