

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Reviewed:	QA	Karolina Nilsson - KARNIL	2021-01-28 - 17:08
Approved:	DD	Diana Tieger - DIATIE	2021-01-29 - 08:40
Released:	QA	Alexandra Holmberg - ALEHOL	2021-02-17 - 12:57

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Released

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.

Product Information

Document ID: PF054-01-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 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, the devices are CE marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material: Lid: Thermoplastic elastomer (TPE) with beige polyethylene (PE) masterbatch
Filter: Acrylic, Polypropylene (PP)
Cassette: Polypropylene (PP), Polyoxymethylene (POM), Silicone oil

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:	Micron HME is single packed in a plastic bag and then 5 or 30 pieces in a cardboard box together with a IFU.

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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Approved:	DD	Fredrik Calais - FRECAL	2020-04-20 - 16:53
Released:	QA	Peter Sundsten - X-PETSUN	2020-06-01 - 11:27

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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

Product Information

Document ID:	PF059-01-TechInfo	Edition:	08
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 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.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	58705 (Tracheostoma protective filter)		
Sterilization:	Non sterile		
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:	Ten Cassettes are packed in a plastic bag and then three bags (total of 30 pcs) are packed together with instructions for use in a cardboard box.		

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
7272-18	Provox XtraFlow HME (20pcs)	07331791013416
7273-18	Provox XtraMoist HME (20PCS)	07331791013423
7290-18	Provox XtraMoist HME (30 PCS)	07331791013430
7291-18	Provox XtraFlow HME (30 PCS)	07331791012358
8229-18	Provox XtraFlow & XtraMoist HME (5+5PCS)	07331791013454

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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Approved:	QA	John Wennborg - JOHWEN	2021-02-03 - 15:09
Released:	DD	Diana Tieger - DIATIE	2021-02-19 - 14:17

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Provox® Coming Home®



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.

Contents in the Coming Home package:

8224SE, 8224NO, 8224DE, 8224CHDE, 8224CHFR, 8224IT, 8224US, 8224AU, 8224PL, 8224GB, 8224CA, 8224GB

- 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
- 10 pcs Provox XtraMoist HME *
- 1 pc Provox Micron **
- 6 pcs Skin Barrier
- 6 pcs Adhesive Remover
- 1 pcs Provox Cleaning Towel
- 1 pcs Provox ShowerAid
- 1 pcs Provox Luna ShowerAid
- 1 pcs Pocket mirror
- 1 pcs Pocket flashlight

*Only applicable for 8224US, **8224DE,8224US does not include Micron.

8224BEFR, 8224BENL, 8224FR, 8224ES, 8224JP, 8224PT, 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 pcs Provox Micron
- 6 pcs Skin Barrier****
- 6 pcs Adhesive Remover*****
- 1 pcs Provox Cleaning Towel
- 1 pcs Provox ShowerAid
- 1 pcs Pocket mirror
- 1 pcs Pocket flashlight

*** 8224JP, 9 pcs. ****8224JP, doesn't contain StabiliBase. *****8224JP, 9 pcs.

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.

Contents in the Life Coming Home package:

8224DA, 8224FI and 8224NL

- 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

Product Information

Document ID: PF-075 01TechInfo **Edition:** 14

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

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 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: N/A

CE Mark: Yes, the devices are CE marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: None-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.

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: 2-30 °C for 8224SE, 8224DA, 8224NO, 8224FI, 8224DE, 8224CHDE, 8224CHFR, 8224IT, 8224NL, 8224US, 8224AU, 8224PL, 8224GB, 8224CA.

Product Information

Temperature limit: 2-42 °C for 8224BEFR, 8224BENL, 8224FR, 8224ES, 8224PT, 8224EM,8224JP.

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.

Devices under Basic UDI-DI:

REF	Name	UDI-DI
8224SE	Provox Coming Home Sweden	07331791009433
8224DK	Provox Life Coming Home Denmark	07331791009440
8224NO	Provox Coming Home Norway	07331791009457
8224FI	Provox Life Coming Home Finland	07331791009464
8224DE	Provox Coming Home Germany	07331791009310
8224NL	Provox Life Coming Home Netherlands	07331791009327
8224FR	Provox Coming Home France	07331791009549
8224ES	Provox Coming Home Spain	07331791009556
8224PT	Provox Coming Home Portugal	07331791009563
8224IT	Provox Coming Home Italy	07331791009570
8224PL	Provox Coming Home Poland	07331791011443
8224GB	Provox Coming Home GB	07331791009587
8224JP	Provox Coming Home Japan	07331791009471
8224CA	Provox Coming Home Canada	07331791009594
8224CHDE	Provox Coming Home Switzerland/German	07331791009600
8224CHFR	Provox Coming Home Switzerland/French	07331791009617
8224BENL	Provox Coming Home Belgium/Dutch	07331791009624
8224BEFR	Provox Coming Home Belgium/French	07331791009631
8224US	Provox Coming Home USA	07331791009334
8224AU	Provox Coming Home Australia	07331791011115
8224EM	Provox Coming Home Generic	07331791011108

Atos Medical AB compatible products: N/A

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

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Released

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.

Product Information

Document ID:	PF077-01-TechInfo	Edition:	04
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 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.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	58705		
Sterilization:	Non-sterile		
Raw material:	Housing: Polydimethylsiloxane (Silicone) 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:	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.		

Product Information

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

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Released:	QA	Peter Sundsten - X-PETSUN	2020-05-25 - 10:40

This document has been electronically signed by the persons above.

Released

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:

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

Product Information

Document ID:	PF077-03-TechInfo	Edition:	02
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 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. <i>Provox Luna HME:</i> 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. <i>Provox Luna Adhesive:</i> 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.		
CE Mark:	Yes, the devices are CE marked.		
GMDN code:	58705		
Sterilization:	Non-sterile		
Raw material:	<i>Provox Luna HME:</i> Housing: Polydimethylsiloxane (Silicone) Foam: Polyurethane (PUR) with calcium chloride (CaCl ₂) <i>Provox Luna Adhesive:</i> Adapter: TPS-SEBS. Carrier: Polyurethane film transparent. Adhesive: HTPU/001 hydrogel with 30 % glycerol. PET, siliconised liner SILPHAN S75M 0R30038 Clear		
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 packed in a plastic bag, 3 adhesives packed in aluminum bags, 1 instructions for use, Packed in a cardboard box		


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

 Atos Medical Your voice	Quality Management System
	<h2>Technical Info / Material Data Sheet</h2>

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Released:	DD	Diana Tieger - DIATIE	2017-05-12 - 09:13

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Document ID: PF081-01Technical Information	Edition: 01
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REF Number 8227SE, 8227DK, 8227NO, 8227FI, 8227DE, 8227NL, 8227FR, 8227ES, 8227PT, 8227IT, 8227GB, 8227JP, 8227CA, 8227CHDE, 8227CHFR, 8227US, 8227AU, 8227EM

Product Name Provox® Living Well™ (followed by Country name and in some cases language)

Models: 18 variants due to country specific information/primary labeling. Content is similar with the exception of:
 Provox Micron, which is excluded in three variants: 8227DE, 8227JP and 8227US
 Provox Luna, which is excluded in 2 variants and exchanged with 3 pcs of Provox OptiDerm and an additional bag of Provox XtraMoist HME: 8227FR, 8227ES, 8227PT
 Provox StabiliBase, which is exchanged with Provox XtraBase in one variant: 8227FR

Classification: Class I (1.1 rule 1)
(MDD 93/42/EEC)

CE Mark: Yes

GMDN code: 58705 (Tracheostoma protective filter)

(U)DI code:

Ref-no	(U)DI code	Ref-no	(U)DI code
8227SE	7331791011290	8227IT	7331791011245
8227DK	7331791011191	8227GB	7331791011238
8227NO	7331791011276	8227JP	7331791011252
8227FI	7331791011214	8227CA	7331791011153
8227DE	7331791011184	8227CHDE	7331791011160
8227NL	7331791011269	8227CHFR	7331791011177
8227FR	7331791011221	8227US	7331791011306
8227ES	7331791011207	8227AU	7331791011122
8227PT	7331791011283	8227EM	7331791011313

Technical Info / Material Data Sheet

Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	Provox Living Well is an assortment of products and information for laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care.
Description:	Included devices are: Provox FlexiDerm Oval (3 pcs), Provox StabiliBase (3 pcs), Provox XtraMoist HME (5 pcs), Provox XtraFlow HME (5 pcs), Provox Luna Adhesive (3 pcs), Provox Luna HME (5 pcs), Provox Micron (1 pcs; excluded in products for Germany, Japan, USA), Provox Cleaning Towel, Provox Skin Barrier (3 pcs) and Provox Adhesive Remover (3 pcs)
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.
Latex information:	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit: 2-30 °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:	The included device with the shortest shelf life upon packing of each lot, will determine the shelf life.
Packaging:	Provox Living Well is a textile bag and each bag is surrounded with a cardboard sleeve holding the label and symbols.

Edition: 01 Release date: 2017-05-12

Document No.: 10000031094

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