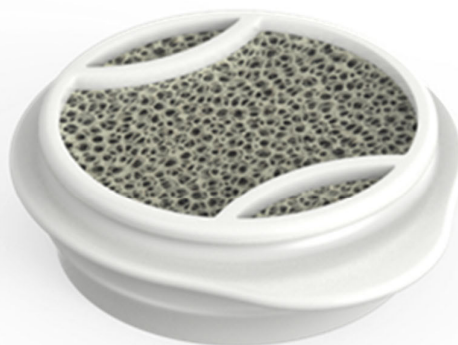


Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Elin Andersson - ELIAND	2022-03-16 - 16:11
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-03-18 - 08:33
Approved:	DD	Mikael Melefors - SEHRBSGM	2022-03-18 - 10:36
Released:	QA	Elin Andersson - ELIAND	2022-03-21 - 15:47

This document has been electronically signed by the persons above.

Product Information

Provox® Life™ FreeHands HME



Product description:

Provox Life FreeHands HME is a heat- and moisture exchanger facilitating pulmonary rehabilitation by humidifying the inhaled air, which helps to keep the lungs healthy.

Document No: 10000040528 Edition: 04 Release date: 2022-03-21

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Product Information

Document ID:	PF099-01-TechInfo	Edition:	04
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	Provox Life FreeHands HME is a single use heat- and moisture exchanger intended for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and in combination with a Provox speaking valve.		
Use specifications:	<p>Intended medical indication Product for rehabilitation for patients breathing through a tracheostoma.</p> <p>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.</p> <p>Intended usage Single use.</p> <p>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.</p> <p>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.</p> <p>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.</p>		
Contraindications:	<p>The products are not intended to be used by patients unable to remove or operate the device, 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 risk for unpredictable periodic loss of consciousness.</p> <p>The product shall not be used by patients with a low tidal volume, as the added dead space may cause CO₂ (Carbon dioxide) retention.</p>		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	58705 (Tracheostoma protective filter)		
Sterilization:	Non-sterile		
Raw material:	Provox Life FreeHands HME is composed of an injection molded polypropylene Housing, assembled with a polyurethane foam (which is impregnated with calcium chloride).		
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:** The HMEs are single packed 10 pieces in a LD-Polyethylen blister sealed with a high barrier polyester-based lidding film. 3 blisters (30 cassettes) are then packed in a cardboard box together with a paper IFU.

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Product Information

Devices under Basic UDI-DI: 7331791-HME-0-000-0008-XZ

REF	Name	UDI-DI
7440	Provox Life FreeHands HME	07731791014895

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands FlexiVoice	7331791-HME-0-000-0007-XW
Provox Life Adhesives	7331791-ADH-0-000-0001-CT
Provox Life LaryTubes	7331791-LTU-0-000-0004-3L