Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Abdallah Almashharawi - ABDALM	2021-12-28 - 10:46
Reviewed:	QA	Elin Algotson - ELIALG	2021-12-28 - 11:28
Approved:	DD	Jon Berg - JONBER	2021-12-29 - 07:00
Released:	QA	Abdallah Almashharawi - ABDALM	2022-04-04 - 09:27

This document has been electronically signed by the persons above.

Atos
atosmedical.com

Product Information

Provox® HME Cap

Product description:

Provox HME Cap is a dome-shaped titanium ring for rehabilitation after total laryngectomy. It allows use of the Provox FreeHands HME Cassettes without the Provox FreeHands HME Speech Valve. The front opening of the cap can be occluded manually to speak.

Document No: 10000043358 Edition: 06 Release date: 2022-04-04

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	PF019-01-TechInfo	**Edition:**	06

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

Classification: (EU) 2017/745 Class I (1.1 Rule)

Intended Use: Provox HME Cap is a single patient use, dome-shaped titanium ring, that allows use of Provox FreeHands HME cassette (REF 8220, 8221) without Provox FreeHands FlexiVoice.

Provox HME Cap is only intended for use when using Provox FreeHands FlexiVoice is not recommended, i.e. when sleeping.

Provox HME Cap cannot be used with any other type of HME cassette.

The front opening of the cap can be occluded manually to speak.

Provox HME Cap can be cleaned and reused.

Use specifications: Intended medical indication: Product for rehabilitation after total laryngectomy.

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 patient use, prescription.

Intended part of the body/type of tissue applied to or interacted with: The product is placed in front of the tracheostoma. 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.

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.

Contraindications: There are no known contraindications.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-Sterile

Raw material: Titanium

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.

Atos
atosmedical.com

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:	5 years after manufacturing.
Packaging:	HME Cap is separately packed in a mini grip plastic bag made of low-density polyethylene together with instructions for use in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-HME-A-000-0002-F2

REF	Name	UDI-DI
7730	Provox HME Cap	07331791003011

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox FreeHands HME Cassette	7331791-HME-0-000-0003-XJ