

# Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Released:	DD	Maria Persson - X-MARPER	2022-01-13 - 14:38

This document has been electronically signed by the persons above.  
**Provox® Protector**



### Product description:

Provox Protector is a reusable cover that provides protection and coverage of the tracheostoma. The Provox Protector is to be placed around the neck during the daytime to be an esthetic coverage and protect against items accidentally entering the tracheostoma. For hygienic reasons, the Provox Protector should be changed daily or sooner if required.

# Product Information

**Document ID:** PF102-01-TechInfo **Edition:** 04

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

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

**Intended Use:** Provox Protector is a reusable cover that provides protection and coverage of the tracheostoma.

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

**Intended patient population:** Patients after a tracheostomy or laryngectomy. Intended to be used by medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

**Intended usage:** Reusable. Hand washing maximum three times and air dried.

**Intended part of the body/type of tissue applied to or interacted with:** Neck and upper body.

**Intended user profile:** Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

**Intended conditions of use:** The Provox Protector act as a protective and cosmetic cover of the tracheostoma for daytime use. Intended for use at home (indoor and outdoor), care facilities and hospitals and exercising under normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.

**Frequency of use:** Daily

**Contraindications:** No identified or known contraindications

**CE Mark:** Yes, the devices are CE marked.

**GMDN code:** 31065 (Tracheostoma protector, reusable)

**Sterilization:** Non-sterile



# Product Information

**Raw material:**

Provox Protector

- Polyester mesh
- Polyurethane foam
- Polyester brushed

Provox Protector Slim

- Polyester mesh
- PP non-woven
- Polyester brushed

Provox Protector Air

- PE spacer mesh
- Cotton textile

**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. Temporary deviations within 2°C - 42°C are allowed.

**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:**

Single packed in polyethylene bag and 10 pcs are packed in cardboard box.

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# Product Information

Devices under Basic UDI-DI: 7331791-TEX-0-000-0001-WN

REF	Name	UDI-DI
7385	Provox Protector Small White 10 pcs	07331791012815
7385	Provox Protector Small White 1 pc	07331791015892
7386	Provox Protector Large White 10 pcs	07331791012822
7386	Provox Protector Large White 1 pc	07331791015908
7387	Provox Protector Slim Small White 10 pcs	07331791012839
7387	Provox Protector Slim Small White 1 pc	07331791015915
7388	Provox Protector Slim Small Blue 10 pcs	07331791012846
7388	Provox Protector Slim Small Blue 1 pc	07331791015922
7389	Provox Protector Slim Large White 10 pcs	07331791012853
7389	Provox Protector Slim Large White 1 pc	07331791015939
7390	Provox Protector Slim Large Blue 10 pcs	07331791012860
7390	Provox Protector Slim Large Blue 1 pc	07331791015946
7391	Provox Protector Air Small White 10 pcs	07331791012877
7391	Provox Protector Air Small White 1 pc	07331791015953
7392	Provox Protector Air Small Blue 10 pcs	07331791012884
7392	Provox Protector Air Small Blue 1 pc	07331791015960
7393	Provox Protector Air Large White 10 pcs	07331791012891
7393	Provox Protector Air Large White 1 pc	07331791015977
7394	Provox Protector Air Large Blue 10 pcs	07331791012907
7394	Provox Protector Air Large Blue 1 pc	07331791015984



**Atos Medical AB Compatible products:**  
Not applicable

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