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This document has been electronically signed by the persons above.

## Product Information

### Provox® Tracheofix



#### Product description:

The Provox Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic coverage of the tracheostoma.

A patient-worn device in the form of a self-adhesive patch designed to protect a tracheostoma orifice against harmful external influences and to absorb secretions; it may also act as a tracheal air filter. It is typically made of porous textile, foam or synthetic fabric materials; it is not intended to be used as a shower shield. This is a single-use device

3 models: 38\*63 mm, 55\*60 mm and 70\*70 mm.

# Product Information

**Document ID:** PF090-01-TechInfo **Edition:** 03

**Manufacturer:** Atos Medical AB  
 Kraftgatan 8, P.O. Box 183,  
 SE-242 22 Hörby, Sweden

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

**Intended Use:** The Provox Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic coverage of the tracheostoma.

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

**GMDN code:** 63378 (Tracheostoma protector, single-use)

**Sterilization:** Non-sterile product

REF	Raw material
1427, 1428, 1435	Elastic polyurethane foam Polyethylene film with acrylate
1429H, 1430H, 1432H, 1433H, 1434H	Polyurethane foam Polyethylene film with acrylate

**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:** 5 years after manufacturing.

**Packaging:** 10 products in Mini-grip bag (PE, 120\*170 mm, 50 µm) with packing slip.

## Product Information

Devices under Basic UDI-DI: 7331791-COM-0-000-0003-58

REF	Name	UDI-DI
1427	Provox Tracheofix 1 strip ivory 55x60	07331791012440
1428	Provox Tracheofix 1 strip ivory 70x70	07331791012457
1435	Provox Tracheofix 2 strips ivory 70x70	07331791012464
1429H	Provox Tracheofix 1 strip beige 55x60	07331791006760
1430H	Provox Tracheofix 1 strip beige 70x70	07331791006777
1432H	Provox Tracheofix 2 strips beige 55x60	07331791006791
1433H	Provox Tracheofix 2 strips beige 70x70	07331791006807
1434H	Provox Tracheofix 1 strip beige 38x63	07331791005985



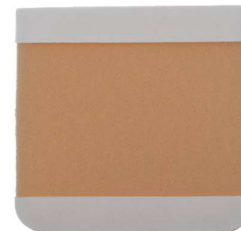
1 strip ivory



2 strips ivory



1 strip beige



2 strips beige

**Atos Medical AB Compatible products:**

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