Product Information

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This document has been electronically signed by the persons above.

TrachPhone®

Product description:

TrachPhone heats and humidifies the inhaled air and partially restores breathing resistance. It can be occluded with a finger to facilitate speech. After release the valve will open automatically. TrachPhone is connected to an ISO 15 tube. An integrated suction port makes it possible to clean the tracheostomy tube from mucus as needed. An oxygen tubing can be connected via the oxygen connector present on TrachPhone.

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

Product Information

Document ID:	PF023-01-TechInfo	**Edition:**	07

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

Classification: (EU) (MDD 93/42/EEC) Class IIa (1.2 Rule 2)

Intended Use: For patients breathing spontaneously via an ET tube or a tracheostomy tube in the hospital or 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: Single use. Over the counter.

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: Do not use beyond recommended tidal volume range, as the added dead space may cause CO2 retention at too low tidal volumes. A too high tidal volume may lead to unsatisfactory humidification.
Do not use on dehydrated patients or patients with very heavy secretions from the lungs and airways.

CE Mark: Yes. Devices are CE-marked.

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-Sterile

Raw material: Polypropylene (PP), thermoplastic elastomers (TPE) and polyurethane (PUR).

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.

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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: TrachPhone is available as 50, 30 and 5 pack.
Each TrachPhone is packed in a plastic bag.
50 / 30 / 5 plastic bags are packed in an inner box (a total of 50 /30 / 5 cassettes).

Devices under Basic UDI-DI: 7331791-HME-0-000-0006-XT

REF	Name	UDI-DI
7704	TrachPhone (50 pcs)	07331791002861
7707	TrachPhone (30 pcs)	07331791009693
7723	TrachPhone (5 pcs)	07331791015854

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Fits on standard 15 mm ISO connector.	N/A