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Released:	QA	Carolina Johansson - SEHRBJNC	2023-04-17 - 12:56

This document has been electronically signed by the persons above.

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Product Information

Provox® BasePlate Adaptor

Product description:

The Provox BasePlate Adaptor ("adaptor") is an accessory product for rehabilitation after total laryngectomy. It allows attaching medical devices, (HME), with ISO 15mm standard connector to a tracheostoma by fitting it into a Provox Adhesive base plate, Provox LaryButton or Provox LaryTube. A typical example would be to attach an HME with built-in oxygen adapter (TrachPhone).

Provox BasePlate Adaptor facilitates the use of TrachPhone together with Provox Adhesives or Provox LaryTube.

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Product Information

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

Classification: (EU) 2017/745 Class I (Rule 1)

Intended Use: Provox BasePlate Adaptor is an accessory that allows attaching medical device, e.g. an HME, with an ISO 15 mm standard connector to a Provox attachment

Use specifications:

Intended medical indication:
Accessory product for patients after total laryngectomy

Intended patient population:
Male and female
Typical average age: N/A.
Cognitive ability, by a clinician judged as sufficient
Manual dexterity: Unconscious patients must be constantly monitored.
Not intended for patients with mechanical ventilation.

Intended usage:
Single patient use.

Intended part of the body/type of tissue applied to or interacted with:
Neck, (tracheostoma).

Intended user profile:
Patient, clinician, trained nurse.

Intended conditions of use:
Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).
Hospital use.
Frequency of use: Continuous use.
Replacement rate: Shall be changed after used for a maximum of 3 months.

Contraindications: Shall not be used for mechanical ventilation

CE Mark: Yes. Device is CE-marked

GMDN code: 58705 (Tracheostoma protective filter)

Sterilization: Non-sterile

Raw material: Polyether ether ketone (PEEK)

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.

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: Provox BasePlate Adaptor is separately packed in a plastic bag of Low Density Polypropylene.
The products and instructions for use are packed in a cardboard box.

Devices under Basic UDI-DI: 7331791-HME-A-000-0003-F5

REF	Name	UDI-DI
7263	Provox BasePlate Adaptor	7331791001697

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38
Provox StabiliBase Provox XtraBase Provox StabiliBase OptiDerm Provox Flexiderm Provox Optiderm	7331791-ADH-0-000-0000-CQ
TrachPhone	7331791-HME-0-000-0006-XT
Freevent DualCare	7331791-HME-0-000-0005-XQ
Freevent XtraCare	7331791-HME-0-000-0004-XM

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