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

Document ID:	PF018-01-TechInfo	**Edition:**	2.0

Manufacturer:
Atos Medical AB
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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 multiple 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.

Operating principles
The Adaptor is an accessory that allows attaching and detaching medical device, e.g. an HME, with an ISO 15 mm standard connector to a Provox attachment or Provox Life attachment. The adaptor shall be cleaned and disinfected before each use to avoid risk of contamination.

Contraindications:
Shall not be used for mechanical ventilation

CE Mark:
Yes. Devices are 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

Product Information

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:	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.

Product Information

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

Document Approvals

Approved Date: 2024-09-29

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