

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sara Dahl - X-SARDAH	2021-12-06 - 11:41
Reviewed:	QA	John Wennborg - JOHWEN	2021-12-07 - 10:01
Approved:	DD	Diana Tieger - DIATIE	2021-12-07 - 10:36
Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:52

This document has been electronically signed by the persons above.

Provox® HME Cassette Adaptor



Product description:

The Provox HME Cassette Adaptor is intended to facilitate a connection between Provox HME Cassette and on the market available tracheal cannulas with ISO-cone (15mm).

For laryngectomies who need a cannula initially or for a longer period of time. Enables immediate start of pulmonary rehabilitation with HME.

Product Information

Document ID:	PF038-01-TechInfo	Edition:	10
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (1.1 Rule 1)		
Intended Use:	The Provox HME Cassette Adaptor is intended to facilitate a connection between Provox HME Cassettes and on the market available tracheal cannulas with ISO-cone (15mm).		
Use specifications:	<p><i>Intended medical indication:</i> For patients breathing through a tracheostoma who use a device with a 15 mm connector. To enable the use of a different diameter HME for pulmonary rehabilitation.</p> <p><i>Intended patient population:</i> Male and female patients breathing through a tracheostoma. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. If not, the operating principle may be performed by someone else than the patient.</p> <p><i>Intended usage:</i> Used together with an HME. Intended for attachment on cannulas with 15 mm ISO connection. Continuous use. Intended part of the body/type of tissue applied to or interacted with: Indirect contact with tissue/bone/dentin via inhaled air.</p> <p><i>Intended user profile:</i> Patient (continuous use and replacement), clinician, trained nurse (primary fitting).</p> <p><i>Intended conditions of use:</i> Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.). Hospital use. Frequency of use: Continuous use. Replacement rate: Replaced after maximum usage for 6 months or sooner if damaged.</p>		
Contraindications:	N/A		
CE Mark:	Yes. Device is CE-marked.		
GMDN code:	63623 (Tracheostomy tube adaptor)		
Sterilization:	Non-sterile		
Raw material:	Silicone		
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:	1 Cassette Adaptor in a plastic bag. 1 IFU

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

REF	Name	UDI-DI
7246	Provox HME Cassette Adaptor	7331791001543

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Xtra HME	7331791-HME-0-000-0000-X9
Provox Micron HME	7331791-HME-0-000-0002-XF
Provox FreeHands HME	7331791-HME-0-000-0003-XJ
Provox ShowerAid	7331791-ADH-A-000-0000-U8