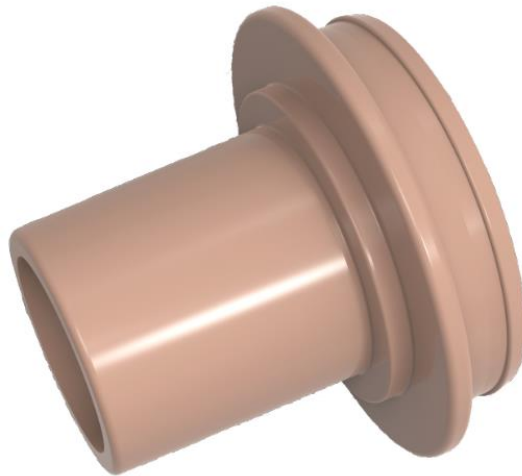


Provox Life BasePlate Adaptor



Product description:

Provox Life BasePlate Adaptor is an accessory that allows attaching and detaching medical devices, e.g. an HME, with an ISO 15 mm standard connector to a Provox Life attachment. The adaptor shall be cleaned between use.

Document ID:	PF018-02-TechInfo	Edition:	2.0
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1.		
Intended Use:	Provox Life BasePlate Adaptor is an accessory that allows attaching medical device, e.g. an HME, with an ISO 15 mm standard connector to a Provox Life 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.		
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		
Biological origin:	The device is not manufactured with materials derived from human or animal source.		

Product Information

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 Life BasePlate Adaptor is separately packed in a plastic bag and together with instructions for use in a cardboard box

Devices under Basic UDI-DI: 7331791-HME-A-000-0005-FB

REF	Name	UDI-DI
8057	Provox Life BasePlate Adaptor	07331791015342

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P
Provox Life Standard Adhesive	7331791-ADH-0-000-0001-CT
Provox Life Sensitive Adhesive	
Provox Life Night Adhesive	
Provox Life Stability Adhesive	
TrachPhone	7331791-HME-0-000-0006-XT
Freevent DualCare	7331791-HME-0-000-0005-XQ
Freevent XtraCare	7331791-HME-0-000-0004-XM
Freevent XtraCare Mini	

Document Approvals
Approved Date: 2024-10-28

Task: Approval Task Verdict: Approve	HUABOD Adrienn Bodonyi, Product Support Specialist (huabod@coloplast.com) Issuer 03-Oct-2024 10:14:19 GMT+0000
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Task: Final Approval Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 28-Oct-2024 06:49:21 GMT+0000