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Released:	QA	Abdallah Almashharawi - ABDALM	2023-02-22 - 07:32

This document has been electronically signed by the persons above.

Product Information

Provox® Flush



Product description:

The Provox Flush device has two components, the Flushing Tube and the Flushing Bladder, which should be assembled by the user. The tip has been designed to fit all sizes of Provox Prosthesis. Squeezing the bladder and there after releasing it allows the flush to be filled with water or air. After sealing the flush against the prosthesis, another squeeze of the bladder will flush water (or air) through the prosthesis. The Flushing tube is bendable to facilitate the best possible seal regardless of tracheoesophageal (TE)-puncture angle.

Product Information

Document ID:	PF006-01-TechInfo	Edition:	11
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class I, Rule 5		
Intended Use:	The Provox Flush is intended to be used to flush drinking water or air through the inner lumen of a Provox voice prosthesis for cleaning purposes. The Flush is intended for both home and clinical use by patient or clinician.		
Use specifications:	<p>Intended medical indication Laryngectomized patients that use voice prostheses, which need cleaning.</p> <p>Intended patient population Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.</p> <p>Intended usage Single patient multiple use, Over-the-counter.</p> <p>Intended part of the body/type of tissue applied to or interacted with: Mucosal membrane.</p> <p>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.</p> <p>Intended conditions of use Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.). Outpatient clinic use. Hospital use. Replacement rate: Max usage for 12 months.</p>		
Contraindications:	None		
CE Mark:	Yes. Devices are CE-marked		
GMDN code:	62096 (Tracheoesophageal speech valve irrigation device)		
Sterilization:	Non-sterile.		
Raw material:	Flushing tube: Polypropylene (PP) with blue masterbatch Flushing Bladder: Silicone.		
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.		
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		

Product Information

Expiration date: 5 years after manufacturing.

Packaging: Provox Flush is separately packed in a plastic bag and then, together with Instructions for use, packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0001-RK

REF	Name	UDI-DI
8109	Provox Flush	07331791005930
8109-18	Provox Flush	07331791013843

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox2 Voice Prosthesis	7331791-VPS-0-0EI-0005-36
Provox Vega	7331791-VPS-0-0EI-0002-2V
Provox NID	7331791-VPS-0-00I-0000-NQ
Provox ActiValve	7331791-VPS-0-00I-0000-NQ