

Provox Swab



Product description:

The Provox Swab is a foam attached to a polymer stick handle.

Document ID:	PF085-01-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 Swab is a single use swab for ex-situ cleaning of Provox LaryTube, Provox LaryButton and tracheostomy inner tubes.		
Use specifications:	Intended medical indication Product for laryngectomized or tracheostomized patients, and/or their caregivers, using Provox LaryTube, Provox LaryButton or double lumen tracheostomy tube, that requires regular cleaning ex-situ. Intended patient population Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. Intended usage Over-the-counter Single patient use, swabs should be discarded after use. Intended part of the body/type of tissue applied to or interacted with N/A, cleaning will be performed ex-situ. Intended user profile Patient, clinician, caregiver. Intended conditions of use Normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc		
Operating principles	The Provox Swab is used for cleaning Provox LaryTube, Provox LaryButton and tracheostomy tubes ex situ by swabbing or brushing (with the swab) the devices		
Contraindications:	No identified or known contraindications		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62956 (Airway device cleaning utensil, noninvasive, single-use)		
Sterilization:	Non sterile		
Raw material:	Polypropylene (stick handle) and Polyurethane, reticulated foam (foam mitt). The materials are in indirect contact with the patient since the product is used when cleaning, ex-situ, The materials will then have contact with the hands and the hands will have contact with the product.		
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:	3 years after manufacturing.
Packaging:	50 pcs per package. Devices are packed in plastic bags made of polyethylene and packed together in a cardboard box with printed instructions for use.

Devices under Basic UDI-DI: 7331791-GEN-A-000-0002-EC

REF	Name	UDI-DI
8250	Provox Swabs Small	07331791011412
8251	Provox Swab Medium	07331791011429
8252	Provox Swab Large	07331791011436
8258	Provox Swab XtraLarge	07331791012730

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 Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P

Document Approvals
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