

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sara Dahl - X-SARDAH	2021-11-11 - 18:58
Reviewed:	QA	John Wennborg - JOHWEN	2021-11-16 - 13:32
Approved:	DD	Diana Tieger - DIATIE	2021-11-16 - 16:11
Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:53

This document has been electronically signed by the persons above.

Released

Document No: 10000038378 Edition: 07 Release date: 2021-12-10

Provox® TubeHolder**Product description:**

The Provox TubeHolder has been developed for use with the Provox LaryTube and Provox LaryButton. The integrated clip connectors allow for optimal fit to the wings of the Provox LaryTube and LaryButton, which reduces the physical stress on the soft silicone material.

Product Information

Document ID:	PF053-01-TechInfo	Edition:	07
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I (Rule 1)		
Intended Use:	The Provox TubeHolder is used for extra support for Provox LaryButton and Provox LaryTube. It goes around the neck of the user and the ends are attached to the "ears" of the LaryTube/LaryButton. The Tubeholder is adjustable in length using a Velcro® connection and allows the user to cut the band to suitable length.		
Use specifications:	<i>Intended medical indication:</i> Patients breathing through a tracheostoma. <i>Intended patient population:</i> Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient. <i>Intended usage:</i> Single use. Intended part of the body/type of tissue applied to or interacted with: The device will contact intact skin on the neck. <i>Intended user profile:</i> The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers. <i>Intended conditions of use:</i> Environment: Home use (normal daily environments without any environmental restrictions regarding temperature, moisture etc.). Hospital use. Frequency of use: Continuous use.		
Contraindications:	None.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	63438 (Tracheostomy tube neck holder, single-use)		
Sterilization:	Non-Sterile		
Raw material:	Tricot textile, Polyurethane (PUR) foam, Polyamide (PA).		
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.		

Product Information

Hazardous components: None.

Expiration date: 5 years after manufacturing.

Packaging: Single packed together with IFU in a plastic bag.

Devices under Basic UDI-DI: 7331791-GEN-A-000-0000-E6

REF	Name	UDI-DI
7668	Provox TubeHolder	07331791002670

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 LaryButton Sizer Kit	7331791-LTU-0-000-0001-3B
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P