

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2022-04-13 - 14:03
Reviewed:	QA	Karolina Nilsson - KARNIL	2022-04-13 - 16:36
Approved:	DD	Diana Tieger - DIATIE	2022-04-14 - 07:59
Released:	QA	Carolina Johansson - SEHRBJNC	2022-05-19 - 15:04

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## Provox® Luna ShowerAid



### Product description:

The Provox Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma.

Document No: 10000030387 Edition: 06 Release date: 2022-05-19

Released

## Product Information

<b>Document ID:</b>	PF079-01-TechInfo	<b>Edition:</b>	06
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1.		
<b>Intended Use:</b>	The Provox Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma. Single patient use.		
<b>Use specifications:</b>	<p><b>Intended medical indication:</b> Laryngectomized patients breathing through a tracheostoma.</p> <p><b>Intended patient population:</b> Male and female. Typical average age for a laryngectomy is 65 years.</p> <p><b>Intended usage:</b> Single patient use.</p> <p><b>Intended part of the body/type of tissue applied to or interacted with:</b> Indirect contact through inhaled air, brief skin contact when attaching the device.</p> <p><b>Intended user profile:</b> Patient, clinician and other caregivers.</p> <p><b>Intended conditions of use:</b> Normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.</p>		
<b>Contraindications:</b>	None		
<b>CE Mark:</b>	Yes. Devices are CE-marked		
<b>GMDN code:</b>	62047		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Polypropylene (PP) with white masterbatch		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		
<b>Packaging:</b>	Provox Luna ShowerAid, 1pc is packed in a plastic bag of polyethylene. The product and instructions for use are packed in a cardboard box.		

## Product Information

Devices under Basic UDI-DI: **7331791-ADH-A-000-0000-U8**

REF	Name	UDI-DI
8016	Provox Luna ShowerAid	07331791009532
8016-18	Provox Luna ShowerAid	07331791014802

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox Luna Adhesive	7331791-ADH-0-000-0000-CQ
Provox Luna Set	7331791-KIT-0-000-0002-HS