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# Product Information

## Provox® Life™ Shower



**Product description:**

Provox Life Shower is a single patient use device intended to be placed into a Provox Life attachment to avoid water from entering the tracheostoma during showering.

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## Product Information

<b>Document ID:</b>	PF088-01-TechInfo	<b>Edition:</b>	09
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
<b>Classification: (EU) 2017/745</b>	Class 1 (Rule 1)		
<b>Intended Use:</b>	Provox Life Shower is a single patient use device intended to be placed into a Provox Life attachment to avoid water from entering the tracheostoma during showering.		
<b>Use specifications:</b>	<p><b>Intended medical indication:</b> Patients breathing through a tracheostoma.</p> <p><b>Intended patient population:</b> Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.</p> <p><b>Intended usage:</b> Single patient multiple use, Over-the-counter.</p> <p><b>Intended part of the body/type of tissue applied to or interacted with:</b> The device will contact intact skin and mucosal membrane and as external communicating device the contact mode with tissue is indirect via air.</p> <p><b>Intended user profile:</b> The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.</p> <p><b>Intended conditions of use:</b> Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.). Outpatient clinic use. Hospital use. Frequency of use: Continuous use. Replacement rate: used for a maximum period of 12 months.</p>		
<b>Contraindications:</b>	No known contraindications		
<b>CE Mark:</b>	Yes. Devices are CE-marked.		
<b>GMDN code:</b>	62047 (Tracheostoma shower shield)		
<b>Sterilization:</b>	Non-Sterile		
<b>Raw material:</b>	Polypropylene (PP) with a violet master batch		
<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.		



# Product Information

**Hazardous components:** None

**Expiration date:** 3 years after manufacturing.

**Packaging:** Provox Life Shower, 1pc is packed in a plastic bag of polyethylene. The product and instructions for use are packed in a cardboard box.

**Devices under Basic UDI-DI:** 7331791-ADH-A-000-0001-UB

REF	Name	UDI-DI
8308	Provox Life Shower	07331791011375

**Atos Medical AB compatible products:**

Range	BASIC UDI-DI
Provox Life Adhesive	7331791-ADH-0-000-0001-CT
Provox Life LaryTube	7331791-LTU-0-000-0004-3L
Provox Life LaryButton	7331791-LTU-0-000-0005-3P

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