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This document has been electronically signed by the persons above.

Product Information

Provox® ShowerAid



Product description:

The Provox ShowerAid is used to temporarily replace the HME during showering. The ShowerAid can be placed in all Provox appliance holders.

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Released

Product Information

Document ID:	PF020-01-TechInfo	Edition:	14
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (EU) 2017/745	Class I, Rule 1		
Intended Use:	The Provox ShowerAid is used to temporarily replace the HME during showering. The ShowerAid can be placed in all Provox appliance holders.		
Use specifications:	<p>Intended medical indication: Laryngectomized patients breathing through a tracheostoma.</p> <p>Intended patient population: Male and female. Typical average age for a laryngectomy is 65 years. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.</p> <p>Intended usage: Single patient use.</p> <p>Intended part of the body/type of tissue applied to or interacted with: Skin.</p> <p>Intended user profile: Patient.</p> <p>Intended conditions of use: Home use (normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.).</p>		
Contraindications:	There are no contraindications for Provox ShowerAid.		
CE Mark:	Yes. Devices are CE-marked.		
GMDN code:	62047 (Tracheostoma shower shield)		
Sterilization:	Non-sterile		
Raw material:	Polypropylene (PP) with blue masterbatch.		
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: The Shower Aid is packed in a OPET/PE plastic bag that is packed together with instructions for use in a cardboard box also including one piece of Provox FlexiDerm Oval.

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

REF	Name	UDI-DI
7260	Provox ShowerAid	7331791001680
7260-18	Provox ShowerAid	7331791014796

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox StabiliBase	7331791-ADH-0-000-0000-CQ
Provox XtraBase	7331791-ADH-0-000-0000-CQ
Provox StabiliBase OptiDerm	7331791-ADH-0-000-0000-CQ
Provox Flexiderm	7331791-ADH-0-000-0000-CQ
Provox Optiderm	7331791-ADH-0-000-0000-CQ
Provox LaryTube	7331791-LTU-0-000-0002-3E
Provox LaryButton	7331791-LTU-0-000-0000-38