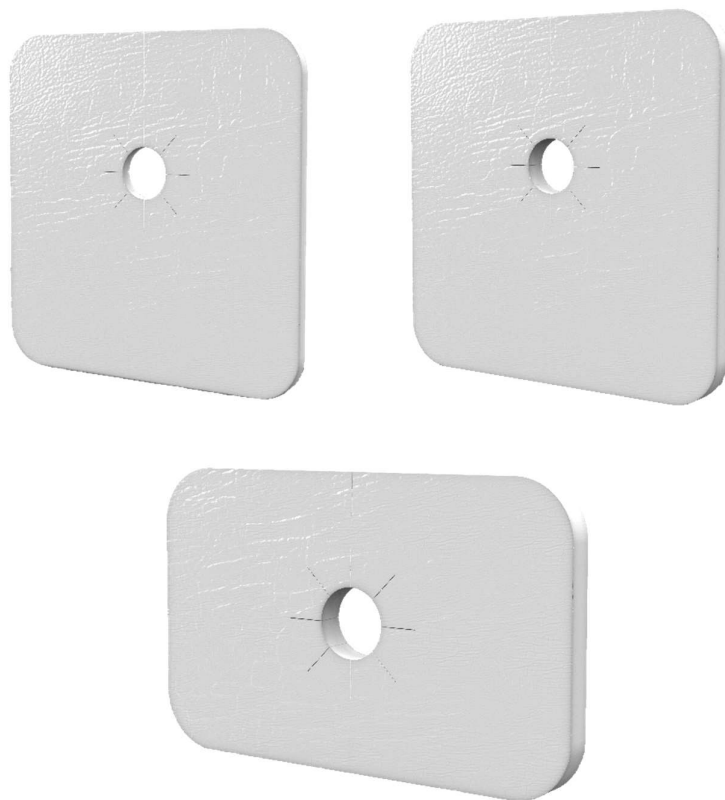


Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Niki Svensson - NIKSVE	2022-11-29 - 11:10
Reviewed:	QA	Sofia Thomasson - SOFTHO	2022-11-29 - 11:23
Approved:	QA	Elin Andersson - ELIAND	2022-11-29 - 13:41
Released:	QA	Niki Svensson - NIKSVE	2023-04-13 - 13:06

This document has been electronically signed by the persons above.

Freevent® Dressing



Product description:

Freevent Dressings are sterile single use dressings that absorb secretion and provide protection for the skin around the tracheostomy tube for patients with a tracheostoma. Freevent Dressing Softfoam is made of soft polyurethane foam that provides medium to high absorption of secretion. Freevent Dressings Softfoam comes in three different sizes with a perforated slit and standard white.

Product Information

Document ID:	PF095-02-TechInfo	Edition: 07
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden	
Classification: (MDD 93/42/EEC)	Class Is (1.4 rule 4)	
Intended Use:	Freevent Dressings are sterile single use dressings that absorb secretion and provide protection for the skin around the tracheostomy tube for patients with a tracheostoma.	
Use specifications:	<p>Intended medical indication Patients using a tracheostomy tube.</p> <p>Intended patient population Adult and pediatric patients using a tracheostomy tube. Intended to be used by medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.</p> <p>Intended usage Single use, Over-the-counter.</p> <p>Intended part of the body/type of tissue applied to or interacted with: Skin around the tracheostoma.</p> <p>Intended user profile Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able by a clinician to manage the device independently.</p> <p>Intended conditions of use Freevent Dressings are for single use and for daily continuous use. Intended for use at home (indoor and outdoor), care facilities and hospitals, during rest, sleep and exercising under normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc. The products are sterilized.</p>	
Contraindications:	There are no known contraindications	
CE Mark:	Yes. Devices are CE-marked.	
GMDN code:	15624 (Tracheostomy tube dressing, sterile)	
Sterilization:	Freevent Dressing Softfoam is gamma sterilized.	
Raw material:	Polyurethane foam and Polyurethane film	



Product Information

- 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 5°C - 30°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:**

REF 8034 and 8035 is individually packed in a paper-polyethylene pouch (12 x 14 cm). 20 pouches are packed in one card-board box with matte film (12.5 x 11.5 x 14.5 cm) together with instructions for use.

REF 8036 is individually packed in a paper-polyethylene pouch (12 x 14 cm). 20 pouches are packed in one card-board box with matte film (12.5 x 7.5 x 14.5 cm) together with instructions for use.

Document No: 10000040640 Edition: 07 Release date: 2023-04-13

Released

Product Information

Devices under Basic UDI-DI: 7331791-COM-0-0G0-0002-J7

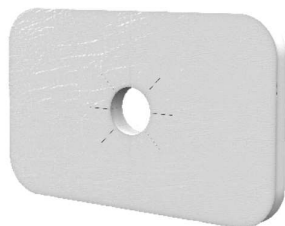
REF	Name	UDI-DI
8034	Freevent Dressing Softfoam L	07331791014086
8035	Freevent Dressing Softfoam S	07331791014093
8036	Freevent Dressing Softfoam Slim L	07331791014109



Freevent Dressing SoftFoam Slim L
(80 x 80 x 2,5 mm)



Freevent Dressing SoftFoam L
(80 x 80 x 5 mm)



Freevent Dressing SoftFoam S
(80 x 50 x 5 mm)

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A

Document No: 10000040640 Edition: 07 Release date: 2023-04-13

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