

Product Information

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This document has been electronically signed by the persons above.



Product description:

The Freevent Dressings are single use tracheal dressings that provide protection between the tracheal cannula and the skin and absorb secretions.

REF	Models
1425, 14251, 14251-PED, 1425932, 1425933, 18008-001	The Tracheostomy dressing, AL coated provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The aluminum metallized side prevents sticking to the skin.
142510, 142512, 142512-PED, 142514, 142516	The Tracheostomy dressing double provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The Tracheostomy dressing double is intended for patients with strong secretion.

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14255, 14255H, 14253, 14253H, 14253H-PED, 14253-PED, 14257, 14259, 14259H	The Tracheostomy dressing combi provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The front side is covered by a washable polyurethane film that prevents soaking of the underlying fleece layers.
142511, 142513, 142515	The Tracheostomy dressing double, AL coated provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The aluminum metallized side prevents sticking to the skin. The Tracheostomy dressing double, AL coated is intended for patients with strong secretion.
14250, 14250-PED, 1425921, 1425923	The Tracheostoma dressing provides protection between the tracheostoma and the tracheostoma tube and prevents adhesion to skin. The fleece material absorbs secretions from the tracheostoma.
14254, 14256, 14258, 14256H	The Tracheostomy dressing combi, AL coated provides protection between the tracheostoma and the tracheostomy tube. The fleece material absorbs secretions from the tracheostoma. The aluminum metallized side prevents sticking to the skin. The front side is covered by a washable polyurethane film that prevents soaking the underlying fleece layers.

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Manufacturer: Atos Medical AB
 Kraftgatan 8
 SE-242 35 Hörby, Sweden

Classification: (EU) Class I (1.4 rule 4)
2017/745

Intended Use: The Freevent Dressings are single use tracheal dressings that provide protection between the tracheal cannula and the skin and absorb secretions.

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Product Information

Use specifications:

- Intended medical indication: Patients using a tracheostomy tube.
- 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.
- Intended usage: Single use.
- Intended part of the body/type of tissue applied to or interacted with: Skin around tracheostoma.
- Intended user profile: Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.
- 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.
- Frequency of use: Continuous use, can be used during night.

Contraindications: None

CE Mark: Yes, the devices are CE marked.

GMDN code: 15624 (Tracheostomy tube dressing)

Sterilization: Non-sterile

Raw material:

REF	Raw material
1425, 14251, 14251-PED, 18008-001	Polyester, Polypropylene and polyester fibers Viscose fleece
14250, 14250-PED	Viscose, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers Viscose fleece
1425921, 1425923	Viscose, polyester and polyamide fibers, Polyethylene
1425932, 1425933	Polyester, Polypropylene and polyester fibers, Viscose fleece
14253, 14255, 14257, 14259, 14253-PED	Viscos, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers. Thermoplastic elastomeric polymers and additives, Polyester/Cotton
14253H, 14255H, 14256H, 14259H, 14253H-PED	Viscose, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers. Thermoplastic elastomeric polymers and additives, Polyester/Cotton
14254, 14256, 14258	Polyester, Polypropylene and polyester fibers. Thermoplastic elastomeric polymers and additives, Polyester/Cotton
142510, 142512, 142514, 142516, 142512-PED	Viscose, polyester and polyamide fibers, Polyethylene, Polyester/Cotton
142511, 142513, 142515	Viscose, polyester and polyamide fibers, Polyethylene, Polypropylene and polyester fibers Polyester, Polyester/Cotton

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 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
Expiration date:	5 years after manufacturing.

Packaging:	REF	Packaging
	1425, 14250, 14250-PED 14251, 14251-PED, 142512, 142512-PED, 1425921, 1425932, 18008-001	10 products in Mini-grip bag (Polyethylene, 120*170 mm, 50 µm) with Instructions for Use.
	1425933, 142510, 142514, 142516 14255, 14255H, 14253, 14253H, 14253H-PED, 14253-PED, 14257 142511, 142513, 142515, 14259, 14259H, 1425923, 14254, 14256, 14258, 14256H	10 products in Mini-grip bag (Polyethylene, 160*220 mm, 50 µm) with Instructions for Use.

Product Information

Devices under Basic UDI-DI: 7331791-COM-0-000-0001-52

REF	Name	UDI-DI
1425	Freevent Dressing AL 80x100	07331791006562
14250	Freevent Dressing slt 90x100	07331791012488
14251	Freevent Dressing AL slt 80x100	07331791006579
14253	Freevent Dressing Combi slt 90x100	07331791006647
14254	Freevent Dressing Combi AL slt 90x100	07331791006654
14255	Freevent Dressing Combi 90x100	07331791006661
14256	Freevent Dressing Combi AL 90x100	07331791006685
14257	Freevent Dressing Combi slt 90x150	07331791006708
14258	Freevent Dressing Combi AL slt 90x150	07331791006715
14259	Freevent Dressing Combi 90x150	07331791012808
142510	Freevent Dressing Dbl 90x100	07331791006586
142511	Freevent Dressing Dbl AL 90x100	07331791006593
142512	Freevent Dressing Dbl slt 90x100	07331791006609
142513	Freevent Dressing Dbl AL slt 90x100	07331791006616
142514	Freevent Dressing Dbl 90x150	07331791006623
142515	Freevent Dressing Dbl AL slt 90x150	07331791012563
142516	Freevent Dressing Dbl slt 90x150	07331791006630
1425921	Freevent Trach Dressing slt 90x100	07331791006722
1425923	Freevent Trach Dressing slt 90x150	07331791006739
1425932	Freevent Dressing AL slt 90x100	07331791006739
1425933	Freevent Dressing AL slt 90x150	07331791006753
14250-PED	Freevent Dressing slt 65x70 PED	07331791012495
142512-PED	Freevent Dressing Dbl slt 65x70	07331791012556
14251-PED	Freevent Dressing AL slt 65x70	07331791012471
14253H	Freevent Dressing Combi BG slt 90x100	07331791012501
14253H-PED	Freevent Dressing Combi BG slt 65x70	07331791012532
14253-PED	Freevent Dressing Combi slt 65x70	07331791012549
14255H	Freevent Dressing Combi BG 90x100	07331791006678
14256H	Freevent Dressing Combi AL/BG 90x100	07331791006692
14259H	Freevent Dressing Combi BG slt 90x150	07331791012792
18008-001	Freevent Dressing AL 65x70 PED	07331791006135

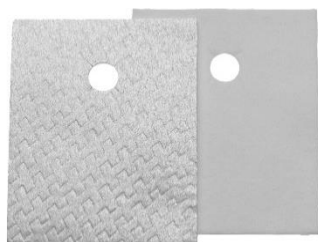


Freevent Dressing slt

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Product Information



Freevent Dressing AL



Freevent Dressing AL slt



Freevent Dressing Combi



Freevent Dressing Combi slt



Freevent Dressing Combi AL



Freevent Dressing Combi AL slt



Freevent Dressing Combi AL/BG

Product Information



Freevent Dressing Combi BG slit



Freevent Dressing Combi BG slit



Freevent Dressing Dbl



Freevent Dressing Dbl slit



Freevent Dressing Dbl AL



Freevent Dressing Dbl AL slit

Atos Medical AB Compatible products:

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