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Issued:	DD	Pontus Eklund - X-PONEKL	2020-04-21 - 14:27
Reviewed:	DD	Jon Berg - JONBER	2020-04-21 - 15:02
Approved:	DD	Fredrik Calais - FRECAL	2020-04-21 - 16:14
Released:	DD	Jon Berg - JONBER	2020-05-28 - 15:09

This document has been electronically signed by the persons above.

Product Information

Freevent® Clothing Stoma Cover



Product description:

The Freevent Clothing Cover is a reusable clothing cover that provides protection and coverage of the tracheostoma.

The Clothing cover works a cosmetic cover for the tracheostoma.

Product Information

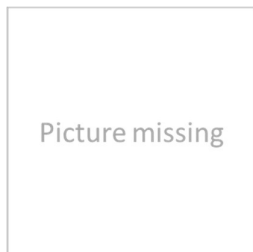
Document ID:	PF091-01-TechInfo	Edition:	02								
Manufacturer:	Atos Medical AB Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden										
Classification: (EU) 2017/745	Class I (1.1 rule 1)										
Intended Use:	The Freevent Clothing Cover is a reusable clothing cover that provides protection and coverage of the tracheostoma.										
CE Mark:	Yes, the devices are CE marked.										
GMDN code:	31065 (Tracheostoma protector, reusable)										
Sterilization:	Non-Sterile										
Raw material:	<table border="1"> <thead> <tr> <th>REF</th> <th>Raw material</th> </tr> </thead> <tbody> <tr> <td>1400, 14001, 140011, 1401, 14011, 14012, 1402, 14022, 14023, 1403, 14033, 14034</td> <td>Polyester, Cotton and Polyamide.</td> </tr> <tr> <td>1413RSR1, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9, 1413RSR11, 1413RSR15, 1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6</td> <td>Polyester, Cotton, Elastan and Polyamide.</td> </tr> <tr> <td>1410A15BP, 1410A21BP, 1410A3BP, 1410A4BP, 1410A5BP, 1410A7BP, 1410A15TG, 1410A1TG, 1410A3TG, 1410A4TG, 1410A5TG, 1410A9TG</td> <td>Polyester, Cotton, Polyamide and Polyurethane</td> </tr> </tbody> </table>			REF	Raw material	1400, 14001, 140011, 1401, 14011, 14012, 1402, 14022, 14023, 1403, 14033, 14034	Polyester, Cotton and Polyamide.	1413RSR1, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9, 1413RSR11, 1413RSR15, 1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6	Polyester, Cotton, Elastan and Polyamide.	1410A15BP, 1410A21BP, 1410A3BP, 1410A4BP, 1410A5BP, 1410A7BP, 1410A15TG, 1410A1TG, 1410A3TG, 1410A4TG, 1410A5TG, 1410A9TG	Polyester, Cotton, Polyamide and Polyurethane
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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:	Single-pack in Mini-grip bag (120x170 or 160x220) with packing slip.										

Product Information

Devices under Basic UDI-DI: 7331791-TEX-0-000-0000-WK

REF	Name	UDI-DI
1400	Clothing cover White 3ply Velcro closure	07331791006142
1401	Clothing cover White 4ply Velcro closure	07331791006173
1402	Clothing cover White 8ply Velcro closure	07331791012624
1403	Clothing cover White 12ply Velcro closure	07331791006258
14001	Clothing cover Beige 3ply Velcro closure	07331791006159
14011	Clothing cover Blue 4ply Velcro closure	07331791006180
14012	Clothing cover Beige 4ply Velcro closure	07331791006197
14022	Clothing cover Beige 8ply Velcro closure	07331791006227
14023	Clothing cover Blue 8ply Velcro closure	07331791006234
14033	Clothing cover Beige 12ply Velcro closure	07331791006265
14034	Clothing cover Blue 12ply Velcro closure	07331791006272
140011	Clothing cover blue 3ply Velcro closure	07331791012617
1410A1TG	Clothing scarf, blue with white dots TG	07331791007071
1410A3BP	Clothing scarf, white cotton/polyester	07331791007101
1410A3TG	Clothing scarf, white trevira-georgette	07331791007095
1410A4BP	Clothing scarf, black cotton/polyester	07331791007125
1410A4TG	Clothing scarf, black trevira-georgette	07331791007118
1410A5BP	Clothing scarf, vine red cotton/polyester	07331791007149
1410A5TG	Clothing scarf, vine red trevira-george	07331791007132
1410A7BP	Clothing scarf, beige cotton/polyester	07331791007170
1410A9TG	Clothing scarf speckled black'n white TG	07331791007194
1410A15BP	Clothing scarf, dark blue cotton/polyester	07331791007231
1410A15TG	Clothing scarf, dark blue trevira-george	07331791007224
1410A21BP	Clothing scarf, grey cotton/polyester	07331791007262
1413RSR1	Clothing round neck T-shirt w zip lock white	07331791006449
1413RSR2	Clothing round neck T-shirt w zip lock beige	07331791006470
1413RSR3	Clothing round neck T-shirt w zip lock yellow	07331791012686
1413RSR4	Clothing round neck T-shirt w zip lock light blue	07331791006487
1413RSR6	Clothing round neck T-shirt w zip lock red	07331791006494
1413RSR7	Clothing round neck T-shirt w zip lock d.green	07331791012693
1413RSR8	Clothing round neck T-shirt w zip lock blue	07331791006500
1413RSR9	Clothing round neck T-shirt w zip lock black	07331791006517
1413RSR11	Clothing round neck T-shirt w zip grey	07331791006456
1413RSR15	Clothing round neck T-shirt w zip lock d.brown	07331791012679
1414RS1	Clothing round neck T-shirt form white	07331791006524
1414RS2	Clothing round neck T-shirt form beige	07331791012709
1414RS3	Clothing round neck T-shirt form light blue	07331791006531
1414RS4	Clothing round neck T-shirt form green	07331791012716
1414RS5	Clothing round neck T-shirt form blue	07331791006548
1414RS6	Clothing round neck T-shirt form black	07331791006555

Product Information



Clothing cover - Velcro closure



Clothing scarf



Clothing round neck T-shirt w zip lock



Clothing round neck T-shirt form

Atos Medical AB Compatible products:

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