 Atos Medical Your voice	Quality Management System
	<h2>Technical Info / Material Data Sheet</h2>

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Renée Nobach - RENNOB	2018-06-14 - 09:28
Reviewed:	QA	John Wennborg - JOHWEN	2018-06-14 - 14:26
Approved:	DD	Jon Berg - JONBER	2018-06-14 - 15:19
Released:	DD	Alexandra Holmberg - ALEHOL	2018-07-05 - 08:08

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REF Number 1400, 14001, 140011, 1401, 14011, 14012, 1402, 14022, 14023, 1403, 14033, 14034, 1413RSR1, 1413RSR11, 1413RSR15, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9, 1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6, 1410A15BP, 1410A15TG, 1410A1TG, 1410A21BP, 1410A3BP, 1410A3TG, 1410A4BP, 1410A4TG, 1410A5BP, 1410A5TG, 1410A7BP, 1410A9TG

Product Name	REF	Product Name
	1400	Clothing cover White 3ply velcro closure
	14001	Clothing cover Beige 3ply velcro closure
	140011	Clothing cover blue 3ply velcro closure
	1401	Clothing cover White 4ply velcro closure
	14011	Clothing cover Blue 4ply velcro closure
	14012	Clothing cover Beige 4ply velcro closure
	1402	Clothing cover White 8ply velcro closure
	14022	Clothing cover Beige 8ply velcro closure
	14023	Clothing cover Blue 8ply velcro closure
	1403	Clothing cover White 12ply velcro closure
	14033	Clothing cover Beige 12ply velcro closure
	14034	Clothing cover Blue 12ply velcro closure
	1413RSR1	Clothing round T-shirt w zip lock white
	1413RSR11	Clothing round neck, T-shirt, zip grey
	1413RSR15	Clothing round T-shirt w zip lock d.brown
	1413RSR2	Clothing round T-shirt w zip lock beige
	1413RSR3	Clothing round T-shirt w zip lock yellow
	1413RSR4	Clothing T-shirt w zip lock light blue
	1413RSR6	Clothing round T-shirt w zip lock red
	1413RSR7	Clothing round T-shirt w zip lock d.green
	1413RSR8	Clothing round T-shirt w zip lock blue
	1413RSR9	Clothing round T-shirt w zip lock black
	1414RS1	Clothing round neck T-shirt form white
	1414RS2	Clothing round neck t-shirt form beige
	1414RS3	Clothing round T-shirt form light blue
	1414RS4	Clothing round neck green
	1414RS5	Clothing round neck T-shirt form blue
	1414RS6	Clothing round neck T-shirt form black
	1410A15BP	Clothing scarf, dark blue cotton/polyses
	1410A15TG	Clothing scarf, dark blue trevira-georg
	1410A21BP	Clothing scarf, grey Cotton/Polyester
	1410A3BP	Clothing scarf, white cotton/polyester
	1410A3TG	Clothing scarf, white trevira-georgette

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1410A4BP	Clothing scarf, black cotton/polyester
1410A4TG	Clothing scarf, black trevira-georgette
1410A5BP	Clothing scarf, vine red cotton/polyest
1410A5TG	Clothing scarf, vine red trevira-george
1410A7BP	Clothing scarf, beige Cotton/Polyester
1410A9TG	Clothing scarf speckled black'n white TG

Models:

REF	Product Name
1400, 14001, 140011, 1401, 14011, 14012, 1402 14022, 14023 1403, 14033, 14034	Clothing cover, in different colours.
1413RSR1, 1413RSR11, 1413RSR15, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9	Clothing T-shirt with zip, in different colours.
1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6	Clothing T-shirt, in different colours.
1410A15BP, 1410A15TG, 1410A1TG, 1410A21BP, 1410A3BP, 1410A3TG, 1410A4BP, 1410A4TG, 1410A5BP, 1410A5TG, 1410A7BP, 1410A9TG	Clothing scarf, in different colours.

Classification: Class I (1.1 rule 1)
(MDD 93/42/EEC)

CE Mark: Yes

GMDN code: 31065 (Tracheostoma protector, reusable)

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(U)DI code:

[EAN code]

REF	Product Name, UDI code
1400	Clothing cover White 3ply velcro closure 7331791006142
14001	Clothing cover Beige 3ply velcro closure 7331791006159
140011	Clothing cover blue 3ply velcro closure 7331791012617
1401	Clothing cover White 4ply velcro closure 7331791006173
14011	Clothing cover Blue 4ply velcro closure 7331791006180
14012	Clothing cover Beige 4ply velcro closure 7331791006197
1402	Clothing cover White 8ply velcro closure 7331791012624
14022	Clothing cover Beige 8ply velcro closure 7331791006227
14023	Clothing cover Blue 8ply velcro closure 7331791006234
1403	Clothing cover White 12ply velcro closure 7331791006258
14033	Clothing cover Beige 12ply velcro closure 7331791006265
14034	Clothing cover Blue 12ply velcro closure 7331791006272
1413RSR1	Clothing round T-shirt w zip lock white 7331791006449
1413RSR11	Clothing round neck, T-shirt, zip grey 7331791006456
1413RSR15	Clothing round Tshirt w zip lock d.brown 7331791012679
1413RSR2	Clothing round T-shirt w zip lock beige 7331791006470
1413RSR3	Clothing round Tshirt w zip lock yellow 7331791012686
1413RSR4	Clothing T-shirt w zip lock light blue 7331791006487
1413RSR6	Clothing round T-shirt w zip lock red 7331791006494
1413RSR7	Clothing round Tshirt w zip lock d.green 7331791012693
1413RSR8	Clothing round T-shirt w zip lock blue 7331791006500
1413RSR9	Clothing round T-shirt w zip lock black 7331791006517
1414RS1	Clothing round neck T-shirt form white 7331791006524
1414RS2	Clothing round neck t-shirt form beige

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	7331791012709
1414RS3	Clothing round T-shirt form light blue 7331791006531
1414RS4	Clothing round neck green 7331791012716
1414RS5	Clothing round neck T-shirt form blue 7331791006548
1414RS6	Clothing round neck T-shirt form black 7331791006555
1410A15BP	Clothing scarf, dark blue cotton/polyses 7331791007231
1410A15TG	Clothing scarf, dark blue trevira-georg 7331791007224
1410A1TG	Clothing scarf, blue with white dots TG 7331791007071
1410A21BP	Clothing scarf, grey Cotton/Polyester 7331791007262
1410A3BP	Clothing scarf, white cotton/polyester 7331791007101
1410A3TG	Clothing scarf, white trevira-georgette 7331791007095
1410A4BP	Clothing scarf, black cotton/polyester 7331791007125
1410A4TG	Clothing scarf, black trevira-georgette 7331791007118
1410A5BP	Clothing scarf, vine red cotton/polyst 7331791007149
1410A5TG	Clothing scarf, vine red trevira-george 7331791007132
1410A7BP	Clothing scarf, beige Cotton/Polyester 7331791007170
1410A9TG	Clothing scarf speckled black'n white TG 7331791007194

Produced by: Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

Intended Use: The FreeVent Clothing Cover is a reusable clothing cover that provides protection and coverage of the tracheostoma.

Description: The Clothing cover works a cosmetic cover for the tracheostoma.

Sterilization: Non-sterile product

Raw material:

REF	Raw material
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1400, 14001, 140011, 1401, 14011, 14012, 1402 14022, 14023 1403, 14033, 14034	<i>Polyester, Cotton and Polyamide.</i>
1413RSR1, 1413RSR11, 1413RSR15, 1413RSR2, 1413RSR3, 1413RSR4, 1413RSR6, 1413RSR7, 1413RSR8, 1413RSR9, 1414RS1, 1414RS2, 1414RS3, 1414RS4, 1414RS5, 1414RS6	<i>Polyester, Cotton, Elastan and Polyamide.</i>
1410A15BP, 1410A21BP, 1410A3BP, 1410A4BP, 1410A5BP, 1410A7BP,	<i>Polyester, Cotton, Polyamide and Polyurethane</i>
1410A15TG, 1410A1TG, 1410A3TG, 1410A4TG, 1410A5TG, 1410A9TG	<i>Polyester, Cotton, Polyamide and Polyurethane</i>

Latex information:	Not manufactured with natural rubber
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight.
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 from manufacturing date




Technical Info / Material Data Sheet

Packaging: Single-pack in Mini-grip bag (120x170 or 160x220) with packing slip.

Edition: 01 Release date: 2018-07-05

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Issued:	DD	Daniel Åberg - DANABE	2020-01-31 - 14:21
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Approved:	DD	Jon Berg - JONBER	2020-01-31 - 18:37
Released:	DD	Daniel Åberg - DANABE	2020-02-06 - 14:28

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REF Number 8034, 8035, 8036, 8038, 8039

Product Name Freevent Dressing Softfoam L
Freevent Dressing Softfoam S
Freevent Dressing Softfoam Slim L
Freevent Dressing Coated L
Freevent Dressing Coated M

Models:

Product	REF and size (width, height thickness)	Models
Softfoam	8034= 80 x 80 x 5 mm 8035= 80 x 40 x 5 mm 8036= 80 x 80 x 2,5 mm	3 models: Different size and lengths, with a perforated slit and standard white.
Coated	8038= 80 x 80 x 2 mm 8039= 80 x 60 x 2 mm	2 models: Different sizes with a permanent slit and standard white.

Classification: Class 1 S (1.4 rule 4)
(MDD
93/42/EEC)


CE Mark: Yes

GMDN code: 15624 (Tracheostomy tube dressing, sterile)

EAN code:

REF	Product Name/ EAN Code
8034	Freevent Dressing Softfoam L
	EAN: 07331791014086
8035	Freevent Dressing Softfoam S
	EAN: 07331791014093
8036	Freevent Dressing Softfoam Slim L
	EAN: 07331791014109
8038	Freevent Dressing Coated L
	EAN: 07331791014116
8039	Freevent Dressing Coated M
	EAN: 07331791014123

Produced by: Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

 Atos Medical Your voice	Quality Management System
	Technical Info / Material Data Sheet

Intended Use: Freeevent Dressings are sterile single use dressings that absorb secretion and provide protection for the skin around the tracheostomy tube for patients with a tracheostoma.

Description: Freeevent Dressing Softfoam is made of soft polyurethane foam that provides medium to high absorption of secretion.

Freeevent Dressing Coated is made of soft viscose that provides low to medium absorption of secretion.

Sterilization: Freeevent Dressing Softfoam= Gamma sterilized
Freeevent Dressing Coated= Ethylene oxide gas

Raw material:	REF	Raw material
	8034	Polyurethane foam
	8035	Polyurethane film
	8036	
	8038	Polypropylene film
	8039	Viscose Polypropylene fabric

Latex information: Not manufactured with natural rubber latex.

Biological origin: The device is not manufactured with any materials derived from human or animal source.

Handling and storage: Keep dry and away from sunlight.


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: 1 years after manufacturing for SoftFoam and 3 years after manufacturing for Coated.

Packaging:

REF	Packaging
8034, 8035	1 product in a paper-polyethylene pouch (12 x 14 cm). 20 pouches in 1 card board box with matte film (12,5 x 11,5 x 14,5 cm).
8036, 8038, 8039	1 product in a paper-polyethylene pouch (12 x 14 cm). 20 pouches in 1 card board box with matte film (12,5 x 7,5 x 14,5 cm).

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REF Number 1425, 14250, 14251, 14253, 14254, 14255, 14256, 14257, 14258, 14259, 142510, 142511, 142512, 142513, 142514, 142515, 142516, 1425921, 1425923, 1425932, 1425933, 14250-PED, 142512-PED, 14251-PED, 14253H, 14253H-PED, 14253-PED, 14255H, 14256H, 14259H, 18008-001.

Product Name FreeVent Tracheostomy dressing AL coated
 FreeVent Trachcompr w slit 90x100mm wh
 FreeVent Trach dressing AL coated w slit
 FreeVent Trach. dress.combi white w slit
 FreeVent Trach dressing combi, AL w slit
 Tracheostomy dressing combi, white
 FreeVent Tracheostomy dressing combi, AL
 FreeVentTrach dress.combi w slit long wh
 FreeVent Trach dress comb AL w slit long
 FreeVentTrach dress.combi long white
 FreeVent Tracheostomy dress double white
 FreeVent Tracheostomy dress.double AL
 FreeVent Trach dressing double w slit wh
 FreeVent Trach dressing double AL w slit
 FreeVent Trach.dress. double white long
 FreeVent Trachdress. double AL slit long
 FreeVent Trach dres double, slit long wh
 Tracheostomy dressing white with slit
 Trach dressing white with slit, long
 Tracheostomy dressing white/AL with slit
 Trach dressing white/AL with slit long
 FreeVent Trachcomp PED w slit 65x70 wh
 FreeVent Trach double compr. PED w slit
 FreeVent Trachcompr PED, slit 65x70 AL
 FreeVent Trach. dress.combi w slit beige
 FreeVentTrach.dres.combi PED w slit beig
 FreeVent Trach.dres. combi PED w slit wh
 FreeVent Tracheostomy dress.combi beige
 FreeVent Trach. dress. combi, AL beige
 FreeVentTrach.dres.comb.beig o/slit long
 FreeVent Tracheostomy dressing AL, mini

Release date: 2018-07-05
Edition: 01

Document No: 1000034908

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Models:

REF	Models
1425, 14251, 14251-PED, 1425932, 1425933, 18008-001	6 models: Different sizes and lengths, with or without slit.
142510, 142512, 142512-PED, 142514, 142516	5 models: Standard, with slit, Pediatric with slit, Standard extra long and with slit extra long.
14255, 14255H, 14253, 14253H, 14253H-PED, 14253-PED, 14257	7 models: Standard white, Standard beige, with slit white, with slit beige, Pediatric with slit beige, Pediatric with slit white, and with slit white extra long.
142511, 142513, 142515	3 models: Standard, with slit, with slit extra long
14250, 14250-PED, 14259, 14259H, 1425921, 1425923,	6 models: Different sizes, lengths, with or without slit.
14254, 14256, 14258, 14256H	4 models: Standard white, Standard beige, with slit white and with slit white extra long

Classification: Class I (1.4 rule 4)
(MDD 93/42/EEC)

CE Mark: Yes

GMDN code: 63324 (Tracheostomy tube dressing, non-sterile)

(U)DI code: [EAN code]

REF	Product Name
1425	FreeVent Tracheostomy dressing AL coated 7331791006562
14250	FreeVent Trachcompr w slit 90x100mm wh 7331791012488
14251	FreeVent Trach dressing AL coated w slit 7331791006579
14253	FreeVent Trach. dress.combi white w slit

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	7331791006647
14254	FreeVent Trach dressing combi, AL w slit 7331791006654
14255	Tracheostomy dressing combi, white 7331791006661
14256	FreeVent Tracheostomy dressing combi, AL 7331791006685
14257	FreeVentTrach dress.combi w slit long wh 7331791006708
14258	FreeVent Trach dress comb AL w slit long 7331791006715
14259	FreeVentTrach dress.combi long white 7331791012808
142510	FreeVent Tracheostomy dress double white 7331791006586
142511	FreeVent Tracheostomy dress.double AL 7331791006593
142512	FreeVent Trach dressing double w slit wh 7331791006609
142513	FreeVent Trach dressing double AL w slit 7331791006616
142514	FreeVent Trach.dress. double white long 7331791006623
142515	FreeVent Trachdress. double AL slit long 7331791012563
142516	FreeVent Trach dres double, slit long wh 7331791006630
1425921	Tracheostomy dressing white with slit 7331791006722
1425923	Trach dressing white with slit, long 7331791006739
1425932	Tracheostomy dressing white/AL with slit 7331791006739
1425933	Trach dressing white/AL with slit long 7331791006753
14250-PED	FreeVent Trachcomp PED w slit 65x70 wh 7331791012495
142512-PED	FreeVent Trach double compr. PED w slit 7331791012556
14251-PED	FreeVent Trachcompr PED, slit 65x70 AL 7331791012471
14253H	FreeVent Trach. dress.combi w slit beige 7331791012501
14253H-PED	FreeVentTrach.dres.combi PED w slit beig 7331791012532
14253-PED	FreeVent Trach.dres. combi PED w slit wh 7331791012549
14255H	FreeVent Tracheostomy dress.combi

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	beige
	7331791006678
14256H	FreeVent Trach. dress. combi, AL beige
	7331791006692
14259H	FreeVentTrach.dres.comb.beig o/slit long
	7331791012792
18008-001	FreeVent Tracheostomy dressing AL, mini
	7331791006135

Produced by: Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

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

Description:

REF	Description
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 aluminium 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.
14255, 14255H, 14253, 14253H, 14253H-PED, 14253-PED, 14257	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 aluminium metallized side prevents sticking to the skin. The Tracheostomy dressing double, AL coated is intended for patients with strong secretion.

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14250, 14250-PED, 14259, 14259H, 1425921, 1425923	The Tracheostoma dressing provides protection between the tracheostoma and the tracheostoma tube and prevents adhesion to wound or 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 aluminium metallized side prevents sticking to the skin. The front side is covered by a washable polyurethane film that prevents soaking the underlying fleece layers.

Sterilization: Non-sterile product

Raw material:

REF	Raw material
1425, 14251, 14251-PED, 18008-001	Polyester Polypropylene and polyester fibres Viscose fleece
14250, 14250-PED	Viscose, polyester och polyamidfibres Polyeten Polypropylene and polyester fibres Viscose fleece
1425921, 1425923	Viscose, polyester och polyamidfibrer polyeten
1425932, 1425933	Polyester Polypropylene and polyester fibres 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

Latex information: Not manufactured with natural rubber

Biological origin: The device is not manufactured with any materials derived from human or animal source.

Handling and storage: Keep dry and away from sunlight.


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 from manufacturing date

Packaging:

REF	Packaging
1425, 14250, 14250-PED 14251, 14251-PED, 142512, 142512-PED, 1425921, 1425932, 18008-001	10 products in Mini-grip bag (PE, 120*170 mm, 50 µm) with packing slip.
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 (PE, 160*220 mm, 50 µm) with packing slip.

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Issued:	DD	Josefine Tillman - JOSTIL	2018-01-31 - 13:16
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Approved:	DD	Mikael Melefors - SEHRBSGM	2018-02-01 - 15:44
Released:	DD	Josefine Tillman - JOSTIL	2018-03-28 - 16:08

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REF Numbers 1520-01, 1520-04, 1530-01, 1530-04, 1580-01, 1580-04, 1590-01, 1590-04

Product Name

REF	Product Name
1520-01	FreeVent NeckStrap Beige, Hook (1 pc)
1520-04	FreeVent NeckStrap Beige, Hook (4 pcs)
1530-01	FreeVent NeckStrap White, Hook (1 pc)
1530-04	FreeVent NeckStrap White, Hook (4 pcs)
1580-01	FreeVent NeckStrap White, Velcro (1 pc)
1580-04	FreeVent NeckStrap White, Velcro (4-pcs)
1590-01	FreeVent NeckStrap Beige, Velcro (1 pc)
1590-04	FreeVent NeckStrap Beige, Velcro (4 pcs)

Models: 8 different models with Plastic Hook or with Velcro. In white or beige color, single or 4-pack.

Classification: Class I (1.1 rule 1)
(MDD 93/42/EEC)

CE Mark: Yes

GMDN code: 35752 (Tracheostomy tube neck holder)

(U)DI code: [EAN code]

REF	Product Name
1520-01	FreeVent NeckStrap Beige, Hook (1 pc) 7331791011450
1520-04	FreeVent NeckStrap Beige, Hook (4 pcs) 7331791011467
1530-01	FreeVent NeckStrap White, Hook (1 pc) 7331791011474
1530-04	FreeVent NeckStrap White, Hook (4 pcs) 7331791011481
1580-01	FreeVent NeckStrap White, Velcro (1 pc) 7331791011498
1580-04	FreeVent NeckStrap White, Velcro (4-pcs) 7331791011504
1590-01	FreeVent NeckStrap Beige, Velcro (1 pc) 7331791011511
1590-04	FreeVent NeckStrap Beige, Velcro (4 pcs) 7331791011528

Technical Info / Material Data Sheet

Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The FreeVent NeckStrap is used to hold a tracheostomy tube in place. It is a reusable, single patient device intended for adult patients using a tracheostomy tube and with sufficient cognitive ability and manual dexterity to allow independent use. Not for pediatric or neonatal use.
Description:	FreeVent NeckStrap is used to hold tracheostomy tube in place by wearing it around the neck. The free ends on FreeVent NeckStrap contain either plastic hooks or Velcro Straps to be used to connect to the "ears" of the tracheostomy tube. The length of FreeVent NeckStrap can be adjusted for an optimal fitting to the tube.
Sterilization:	Non-sterile
Raw material:	<p><u>Hook Version:</u> Hook-Polypropylene Ribbon- Lycra/polyamide, white or beige color</p> <p><u>Velcro Version:</u> Hook and Loop-Velcro Ribbon Lycra/polyamide, white or beige color</p>
Latex information:	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from direct sun light. Hand washes only.
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 from manufacturing date
Packaging:	<p><u>Single-pack version:</u> Single NeckStrap in a protective welded plastic bag. Put in a Mini-grip bag (PE, 80*120 mm, 50 µm) with IFU leaflet and a label.</p> <p><u>4-pack version:</u></p>


Technical Info / Material Data Sheet

Single NeckStrap in a protective welded plastic bag, 4 single packed neckstraps put in a Mini-grip bag (PE, 160*200 mm, 50 µm) with IFU leaflet and a label.

Edition: 00 Release date: 2018-03-28

Document No: 10000031558

Released

 Atos Medical Your voice	Quality Management System
	<h2>Technical Info / Material Data Sheet</h2>

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Mikael Melefors - SEHRBSGM	2018-09-11 - 13:18
Reviewed:	QA	Karolina Nilsson - KARNIL	2018-09-12 - 14:24
Approved:	DD	Jon Berg - JONBER	2018-09-12 - 16:24
Released:	DD	Mikael Melefors - SEHRBSGM	2018-10-05 - 15:40

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Document ID: PF094-01-TECHINFO	Edition: 02
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REF Number: 1577, 1588, 1599, 1699, 1651, 1661, 1652, 1662, 1751, 1761, 1752, 1762

Product Name: FreeVent Flexi-Klett Tube-Holder f. kids
 FreeVent Flexi-Klett extension 25cm
 FreeVent Flexi-Klett Tube-Holder
 FreeVent Flexi-Klett Tube-Holder beige
 FREEVENT Neckband, one-piece, small
 FREEVENT Neckband, one-piece, large
 FREEVENT Neckband, two-piece, small
 FREEVENT Neckband, two-piece, large

Models: Color: white or beige (Flexi-Klett only)
 Adult and Child sizes

Classification: Class I (1.1 rule 1)
 (MDD
 93/42/EEC)

CE Mark: Yes

GMDN code: 63438 (Tracheostomy tube neck holder, single use)

(U)DI code:

REF	Product Name/EAN Code
1577	FreeVent Flexi-Klett Tube-Holder f. kids 07331791012433
1588	FreeVent Flexi-Klett extension 25cm 07331791012426
1599	FreeVent Flexi-Klett Tube-Holder 07331791012419
1699	FreeVent Flexi-Klett Tube-Holder beige 07331791012402
1651	FREEVENT Neckband, one-piece, small 07331791012914
1661	FREEVENT Neckband, one-piece, large 07331791012938
1652	FREEVENT Neckband, two-piece, small 07331791012921
1662	FREEVENT Neckband, two-piece, large 07331791012945
1751	FREEVENT Neckband, one-piece, small 07331791013607
1761	FREEVENT Neckband, one-piece, large 07331791013614
1752	FREEVENT Neckband, two-piece, small 07331791013621
1762	FREEVENT Neckband, two-piece, large 07331791013638

Technical Info / Material Data Sheet

Produced by: Atos Medical AB, Kraftgatan 8, P.O. Box 183, 242 22 Hörby, Sweden

Intended Use: **REF 1577, 1588, 1599 and 1699:**

The FreeVent Flexi-Klett is used to hold a tracheostomy tube in place. It is a single use device intended for adult and pediatric patients using a tracheostomy tube and with sufficient cognitive ability and manual dexterity to allow independent use. Not for neonatal use.

REF 1651, 1661, 1652, 1662, 1751, 1761, 1752 and 1762:

The FREEVENT Neckbands are used for holding a tube/button in place by wearing it around the neck and connecting the ends of the neckband to the tube/button.

Description:

The FREEVENT Neckbands and Flexi-Klett Tube Holders are tube/button holders for patients breathing through a tracheostoma. Two-piece variants connect with hook-and-loop whereas one-piece variants connect with twill ties.

Sterilization: Non-sterile

Raw material: **REF 1577, 1588, 1599 and 1699:**

Polyurethane ester foam with flock coating polyamide, acrylic copolymer glue
Rubber band (57 % polyester, 43 % elastomer)

REF 1651, 1661, 1652, 1662, 1751, 1761, 1752 and 1762:

Nylon, cotton and polyester polyurethane foam.

Latex information:

Not manufactured with natural rubber Latex

Biological origin:

The device is not manufactured with any materials derived from human or animal source.

Handling and storage:

Keep dry and away from sunlight.

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 date

Packaging:

REF 1577, 1588, 1599 and 1699:


Single-pack in Mini-grip bag (polyethylene, 80*120 mm, 50µ) with packing slip.

REF 1651, 1661, 1652 and 1662:

10 pcs in a box, each neckband individually packed in a polybag (polyethylene)

REF 1751, 1761, 1752 and 1762:

100 pcs in a box, each neckband individually packed in a polybag (polyethylene)

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Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Alexandra Holmberg - ALEHOL	2018-04-18 - 08:26
Reviewed:	QA	John Wennborg - JOHWEN	2018-04-19 - 13:27
Approved:	DD	Daniel Åberg - DANABE	2018-04-19 - 13:58
Released:	DD	Alexandra Holmberg - ALEHOL	2018-06-15 - 07:40

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Document ID: PF093-01-TECHINFO	Edition: 00
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REF Number 142700-D,142700-PED,142800,1431

Product Name FreeVent Pad, Adult, 90x100mm, w slit
FreeVent Pad, PED, 65x70 mm w. slit
FreeVent Pad, Adult, 65x45mm
FreeVent Tracheofix with hole

Models: 3 models: unsterile, thickness 3mm:
REF 142700: for adults, 90 x 100 mm, with hole and slit;
REF 142700-PED: for children, 65 x 70 mm, with whole and slit
REF 142800:for adults, 65 x 45 mm, with hole

REF 1431 N/A

Classification: Class I (1.1 rule 1)
(MDD 93/42/EEC)

CE Mark: Yes

GMDN code: 63324 (Tracheostomy tube dressing, non-sterile)

(U)DI code: [EAN code]

REF	Product Name
142700-D	FreeVent Pad, Adult, 90x100mm, w slit 7331791012587
142700-PED	FreeVent Pad, PED, 65x70 mm w. slit 7331791012594
142800	FreeVent Pad, Adult, 65x45mm 7331791012570
1431	FreeVent Tracheofix with hole 7331791006784

Produced by: Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

Technical Info / Material Data Sheet

Intended Use:

Description: REF: The FreeVent Pad provides protection between the tracheostoma and the tracheostomy tube. The PU-foam material absorbs secretions from the tracheostoma. The FreeVent Pad is intended to be used as a cushion between canula and skin and also for patients with strong secretion.

REF: 1431

The Tracheofix with hole is a foam dressing that provides a protection between the tracheostomy tube and the skin. It is intended for patients with small secretion.

Sterilization: Non-sterile product

Raw material: REF: Polyether Polyurethane foam

REF: 1431

Polyurethane foam

Latex information: Not manufactured with natural rubber

Biological origin: The device is not manufactured with any materials derived from human or animal source.

Handling and storage: Keep dry and away from sunlight.

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 from manufacturing date

Packaging: REF 142700 and REF 142700-PED:
15 products single packed (PE, 120*120 mm, 50 µm) in paper box.
Instructions for use attached

REF 142800:
30 products single packed (PE, 70*10 mm, 50 µm) in paper box.
Instructions for use attached

REF 1431:
10 products in Mini-grip bag (PE, 120*170 mm, 50 µm) with packing slip.
Instructions for use attached.

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Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Diana Tieger - DIATIE	2017-10-24 - 21:18
Reviewed:	DD	Mikael Melefors - SEHRBSGM	2017-10-25 - 20:23
Approved:	QA	John Wennborg - JOHWEN	2017-10-27 - 07:27
Released:	DD	Alexandra Holmberg - ALEHOL	2017-11-01 - 17:01

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Document ID: PF084-02 TechInfo	Edition: 02
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REF Number	1602
Product Name	FreeVent Tracheal Tube Cleansing Jar
Models:	N/A
Classification: (MDD 93/42/EEC)	Class I (1.1 rule 1)
CE Mark:	Yes
GMDN code:	62628 (Artificial airway washing/disinfection jar)
(U)DI code:	None
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The FreeVent Tracheal Tube Cleansing Jar is intended for cleaning of all types of tracheal tubes with FreeVent Tracheal Tube Detergent Powder
Description:	Jar for cleaning of tracheal tubes
Sterilization:	Non-sterile
Raw material:	Polypropylene (jar)
Latex information:	The device is not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from direct sun light
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

Technical Info / Material Data Sheet


Expiration date: Shelf life, 5 years

Packaging: Single package

Edition: 02 Release date: 2017-11-01

Document No: 10000031086

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 Atos Medical Your voice	Quality Management System
	<h2>Technical Info / Material Data Sheet</h2>

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Mikael Melefors - SEHRBSGM	2017-07-05 - 15:47
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Approved:	DD	Rolf Karlberg - SEHRBKGR	2017-07-06 - 09:08
Released:	DD	Alexandra Holmberg - ALEHOL	2017-11-01 - 17:01


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Document ID: PF084-01 TechInfo	Edition: 01
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REF Number	1601
Product Name	FreeVent Tracheal Tube Detergent Powder
Models:	N/A
Classification: (MDD 93/42/EEC)	Class I (1.1 rule 1)
CE Mark:	Yes
GMDN code:	38773 (Medical device decontamination agent)
(U)DI code:	None
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The FreeVent Tracheal Tube Detergent Powder is intended for cleaning of all types of tracheal tubes.
Description:	Detergent for cleaning of tracheal tubes.
Sterilization:	Non-sterile
Raw material:	Anionic tensides (5-15%) Non-ionic tensides (<5%) Phosphate (>30%) Metasilicate Corrosion inhibitors Color Pigment Polypropylene (jar)
Latex information:	The device is not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from direct sun light Temperature limits 5-25 °C

Technical Info / Material Data Sheet

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:	<p>Indications of danger: C - Corrosive</p> <p>R phrases:</p> <p>Causes burns.</p> <p>Irritating to respiratory system.</p> <p>Classification according to Regulation (EC) No. 1272/2008 [CLP]</p> <p>Hazard categories:</p> <p>Substance or mixture corrosive to metals: Met. Corr. 1</p> <p>Skin corrosion/irritation: Skin Corr. 1B</p> <p>Serious eye damage/eye irritation: Eye Dam. 1</p> <p>Specific target organ toxicity - single exposure: STOT SE 3</p> <p>Hazard Statements:</p> <p>May be corrosive to metals.</p> <p>Causes severe skin burns and eye damage.</p> <p>May cause respiratory irritation.</p>
Expiration date:	36 months
Packaging:	Jar with 400 g powder

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	<h2>Technical Info / Material Data Sheet</h2>

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Fredrik Lostrup - X-FRELOS	2017-03-30 - 14:04
Reviewed:	QA	Karolina Nilsson - KARNIL	2017-04-06 - 17:36
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Released:	DD	Mikael Melefors - SEHRBSGM	2018-01-02 - 16:25

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Document ID: PF082 TechInfo	Edition: 00
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REF Number	1205, 1206, 1207, 1208, 1209, 1210.
Product Name	FreeVent TubeBrush.
Models:	5 brush models with outer diameter (bristles): 6, 8, 10, 12 and 14 mm. REF Number 1210 is a set of 3 brushes (8, 10 and 12 mm).
Classification: (MDD 93/42/EEC)	Class I (1.1 Rule 1)
CE Mark:	Yes.
GMDN code:	34883 (Airway device, cleaning brush, noninvasive).
(U)DI code:	N/A
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The FreeVent TubeBrush is used for cleaning of tracheostomy tubes ex situ.
Description:	The brushes are available in 5 different models with different outer diameter.
Sterilization:	Non-sterile.
Raw material:	ABS, Stainless Steel, Polybutylene Terephthalate PBT, Cotton.
Latex information:	Latex free.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from direct sun light
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.

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Expiration date: 3 years after manufacturing.

Packaging: 10 brushes in each package except for FreeVent TubeBrush set (1210) which includes 3 brushes (8, 10 and 12 mm) in each package.

Edition: 00 Release date: 2018-01-02

Document No: 10000031450

Released

 Atos Medical Your voice	Quality Management System
	<h2>Technical Info / Material Data Sheet</h2>

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Mårten Cervin - SEHRBCNM	2019-09-24 - 12:58
Reviewed:	QA	Karolina Nilsson - KARNIL	2019-09-25 - 10:43
Approved:	DD	Daniel Åberg - DANABE	2019-09-25 - 20:17
Released:	DD	Mårten Cervin - SEHRBCNM	2019-10-01 - 10:54

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Document ID: PF090-01-TECHINFO	Edition: 01
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REF Number & Product Name	1427	Provox® Tracheofix 1 strip ivory 55x60
	1428	Provox® Tracheofix 1 strip ivory 70x70
	1435	Provox® Tracheofix 2 strips ivory 70x70
	1429H	Provox® Tracheofix 1 strip beige 55x60
	1430H	Provox® Tracheofix 1 strip beige 70x70
	1432H	Provox® Tracheofix 2 strips beige 55x60
	1433H	Provox® Tracheofix 2 strips beige 70x70
	1434H	Provox® Tracheofix 1 strip beige 38x63

Models: 3 models: 38*63 mm, 55*60 mm and 70*70 mm.

Classification: Class I (1.1 rule 1)
(MDD
93/42/EEC)


CE Mark: Yes

GMDN code: 63378 (Tracheostoma protector, single-use)

EAN code:

REF	Description	EAN code
1427	Provox Tracheofix 1 strip ivory 55x60	7331791012440
1428	Provox Tracheofix 1 strip ivory 70x70	7331791012457
1435	Provox Tracheofix 2 strips ivory 70x70	7331791012464
1429H	Provox Tracheofix 1 strip beige 55x60	7331791006760
1430H	Provox Tracheofix 1 strip beige 70x70	7331791006777
1432H	Provox Tracheofix 2 strips beige 55x60	7331791006791
1433H	Provox Tracheofix 2 strips beige 70x70	7331791006807
1434H	Provox Tracheofix 1 strip beige 38x63	7331791005985

Produced by: Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

 Atos Medical Your voice	Quality Management System
	Technical Info / Material Data Sheet

Intended Use: The Provox Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic coverage of the tracheostoma.

Description: A patient-worn device in the form of a self-adhesive patch designed to protect a tracheostoma orifice against harmful external influences and to absorb secretions; it may also act as a tracheal air filter. It is typically made of porous textile, foam or synthetic fabric materials; it is not intended to be used as a shower shield. This is a single-use device

Sterilization: Non-sterile product

Raw material:	REF	Raw material
	1427, 1428, 1435	Elastic polyurethane foam Polyethylene film with acrylate
	1429H, 1430H, 1432H, 1433H, 1434H	Polyurethane foam Polyethylene film with acrylate

Latex information: Not manufactured with natural rubber

Biological origin: The device is not manufactured with any materials derived from human or animal source.

Handling and storage: Keep dry and away from sunlight.

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 from manufacturing date

Packaging: 10 products in Mini-grip bag (PE, 120*170 mm, 50 µm) with packing slip.

Technical Info / Material Data Sheet

Document ID: PF064-01-TechInfo	Edition: 05
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REF Number	1502
Product Name	Stoma Oil
Models:	1 model
Classification: (MDD 93/42/EEC)	IIb (2.1 rule 5)
CE Mark:	Yes
GMDN code:	57897 (Tracheostomy tube lubricant)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	The stoma-oil is intended to be used to moisten the cannula to make the insertion into the stoma easier. It is also intended to lubricate the inner cannula of plastic tracheal cannulas before insertion into the outer cannula.
Description:	The Stoma Oil is make of 100% Coconut oil and comes in a 100 mL bottle.
Sterilization:	Non-sterile.
Raw material:	Caprylic/Capric Acid Triglyceride (MCT).
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2-42°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:	3 years after manufacturing.
Packaging:	Glass bottle, 100 ml, packed in low density polyethylene (LDPE) bubble bag. One Instructions for Use Stoma Oil is included.

Reviewed by:


 Vice President QA&RA

 2016-02-18

 Date

Approved by:


 Vice President Design & Development

 2016-02-22

 Date