Atos
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Document title
Declaration of Conformity

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Issued:	QA	Ulrika Svensson - SEHRBHNU	2020-09-01 - 14:47
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Approved:	OP	Martin Richardson - MARRIC	2020-09-02 - 13:46
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-09-02 - 15:14

This document has been electronically signed by the persons above.

We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing Annex II, with the exemption of section 4 (for class IIa and class IIb devices) and Annex VII (for class I devices) of the European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The Freevent Accessories

REF	Name	Class	GMDN code
FreeVent Dressings			
8034	FREEVENT Dressing Softfoam L	I	15624
8035	FREEVENT Dressing Softfoam S	I	15624
8036	FREEVENT Dressing Softfoam Slim L	I	15624
8038	Freevent Dressing Coated L	I	15624
8039	Freevent Dressing Coated M	I	15624
FreeVent Neckbands			
1699	FreeVent Flexi-Klett Tube-Holder beige	I	63438
1599	FreeVent Flexi-Klett Tube-Holder	I	63438
1588	FreeVent Flexi-Klett extension 25cm	I	63438
1577	FreeVent Flexi-Klett Tube-Holder f. kids	I	63438
FreeVent NeckStraps			
1520-01	FreeVent NeckStrap. Beige, Hook (1 pc)	I	35752
1520-04	FreeVent NeckStrap. Beige, Hook (4 pcs)	I	35752
1530-01	FreeVent NeckStrap. White, Hook (1 pc)	I	35752
1530-04	FreeVent NeckStrap. White, Hook (4 pcs)	I	35752
1580-01	FreeVent NeckStrap White, Velcro (1 pc)	I	35752
1580-04	FreeVent NeckStrap White, Velcro (4 pcs)	I	35752
1590-01	FreeVent NeckStrap. Beige, Velcro (1 pc)	I	35752
1590-04	FreeVent NeckStrap. Beige Velcro (4 pcs)	I	35752

Each kind of medical device to which the system has been applied complies with the applicable provisions of the Essential Principles and Essential Requirements, the classification rules, applicable standards and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Valid Certificates are controlled and filed by QA/RA Department. For standards applied see Applicable Standards & Essential Requirements for each product.

Notified Body: *Intertek Semko AB, Sweden. Identification no. 0413*
EC-certificate no. 41310296-03

Competent Authority: *Medical Products Agency, Sweden*

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Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-05 - 09:58

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Freevent® Clothing Stoma Cover

Basic UDI: 7331791-TEX-0-000-0000-WK

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
The Freevent Clothing Cover is a reusable clothing cover that provides protection and coverage of the tracheostoma.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-TEX-0-000-0000-WK

REF	Name	Class	GMDN code
1400	Clothing cover White 3ply Velcro closure	I	31065
1401	Clothing cover White 4ply Velcro closure	I	31065
1402	Clothing cover White 8ply Velcro closure	I	31065
1403	Clothing cover White 12ply Velcro closure	I	31065
14001	Clothing cover Beige 3ply Velcro closure	I	31065
14011	Clothing cover Blue 4ply Velcro closure	I	31065
14012	Clothing cover Beige 4ply Velcro closure	I	31065
14022	Clothing cover Beige 8ply Velcro closure	I	31065
14023	Clothing cover Blue 8ply Velcro closure	I	31065
14033	Clothing cover Beige 12ply Velcro closure	I	31065
14034	Clothing cover Blue 12ply Velcro closure	I	31065
140011	Clothing cover blue 3ply Velcro closure	I	31065
1410A15BP	Clothing scarf, dark blue cotton/polyes	I	31065
1410A15TG	Clothing scarf, dark blue trevira-georg	I	31065
1410A1TG	Clothing scarf, blue with white dots TG	I	31065
1410A21BP	Clothing scarf, grey Cotton/Polyester	I	31065
1410A3BP	Clothing scarf, white cotton/polyester	I	31065
1410A3TG	Clothing scarf, white trevira-georgette	I	31065
1410A4BP	Clothing scarf, black cotton/polyester	I	31065
1410A4TG	Clothing scarf, black trevira-georgette	I	31065
1410A5BP	Clothing scarf, vine red cotton/polyest	I	31065
1410A5TG	Clothing scarf, vine red trevira-george	I	31065
1410A7BP	Clothing scarf, beige Cotton/Polyester	I	31065
1410A9TG	Clothing scarf speckled black'n white TG	I	31065
1413RSR1	Clothing round T-shirt w zip lock white	I	31065
1413RSR11	Clothing round neck, T-shirt, zip grey	I	31065
1413RSR15	Clothing round T-shirt w zip lock d.brown	I	31065
1413RSR2	Clothing round T-shirt w zip lock beige	I	31065
1413RSR3	Clothing round T-shirt w zip lock yellow	I	31065
1413RSR4	Clothing T-shirt w zip lock light blue	I	31065
1413RSR6	Clothing round T-shirt w zip lock red	I	31065
1413RSR7	Clothing round T-shirt w zip lock d.green	I	31065
1413RSR8	Clothing round T-shirt w zip lock blue	I	31065
1413RSR9	Clothing round T-shirt w zip lock black	I	31065
1414RS1	Clothing round neck T-shirt form white	I	31065
1414RS2	Clothing round neck T-shirt form beige	I	31065
1414RS3	Clothing round T-shirt form light blue	I	31065
1414RS4	Clothing round neck green	I	31065
1414RS5	Clothing round neck T-shirt form blue	I	31065
1414RS6	Clothing round neck T-shirt form black	I	31065

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Approved:	OP	Martin Richardson - MARRIC	2020-06-05 - 12:17
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-05 - 13:07

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Freevent® Dressing

Basic UDI: 7331791-COM-0-000-0001-52

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
There are more than one Intended Use in this declaration of conformity. The Intended Use for each group is stated before the group table.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

DECLARATION OF CONFORMITY MDR CLASS I

7331791-COM-0-000-0001-52

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

REF	Name	Class	GMDN code
1425	Freevent Dressing AL 80x100	I	63324
14250	Freevent Dressing slt 90x100	I	63324
14251	Freevent Dressing AL slt 80x100	I	63324
14253	Freevent Dressing Combi slt 90x100	I	63324
14254	Freevent Dressing Combi AL slt 90x100	I	63324
14255	Freevent Dressing Combi 90x100	I	63324
14256	Freevent Dressing Combi AL 90x100	I	63324
14257	Freevent Dressing Combi slt 90x150	I	63324
14258	Freevent Dressing Combi AL slt 90x150	I	63324
14259	Freevent Dressing Combi 90x150	I	63324
142510	Freevent Dressing Dbl 90x100	I	63324
142511	Freevent Dressing Dbl AL 90x100	I	63324
142512	Freevent Dressing Dbl slt 90x100	I	63324
142513	Freevent Dressing Dbl AL slt 90x100	I	63324
142514	Freevent Dressing Dbl 90x150	I	63324
142515	Freevent Dressing Dbl AL slt 90x150	I	63324
142516	Freevent Dressing Dbl slt 90x150	I	63324
1425921	Freevent Trach Dressing slt 90x100	I	63324
1425923	Freevent Trach Dressing slt 90x150	I	63324
1425932	Freevent Dressing AL slt 90x100	I	63324
1425933	Freevent Dressing AL slt 90x150	I	63324
14250-PED	Freevent Dressing slt 65x70 PED	I	63324
142512-PED	Freevent Dressing Dbl slt 65x70	I	63324
14251-PED	Freevent Dressing AL slt 65x70	I	63324
14253H	Freevent Dressing Combi BG slt 90x100	I	63324
14253H-PED	Freevent Dressing Combi BG slt 65x70	I	63324
14253-PED	Freevent Dressing Combi slt 65x70	I	63324
14255H	Freevent Dressing Combi BG 90x100	I	63324
14256H	Freevent Dressing Combi AL/BG 90x100	I	63324
14259H	Freevent Dressing Combi BG slt 90x150	I	63324
18008-001	Freevent Dressing AL 65x70 PED	I	63324

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

REF	Name	Class	GMDN code
142700-D	Freevent Dressing Pad slt 90x100	I	63324
142700-PED	Freevent Dressing Pad slt 65x70 PED	I	63324
142800	Freevent Dressing Pad 65x45	I	63324
1431	Freevent Dressing Foam 70x70	I	63324

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

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Approved:	OP	Martin Richardson - MARRIC	2020-09-02 - 13:44
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-09-02 - 13:49

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Freevent® DualCare™

Basic UDI: 7331791-HME-0-000-0005-XQ

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
There are more than one Intended Use in this declaration of conformity. The Intended Use for each group is stated before the group table.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

DECLARATION OF CONFORMITY MDR CLASS I

7331791-HME-0-000-0005-XQ

Intended Use:
Freevent DualCare is a combined Speaking Valve and Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff. In HME-mode the device conditions inhaled air by retaining heat and moisture from the exhaled air. By turning the lid of the Speaking Valve into speaking mode air is re-directed to enable speech. The entire device is for single patient use and the HME-part is for single use.

Patient Population: For spontaneously breathing tracheostomized patients (adults and pediatric patients greater than 10 kg in weight) using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.

Environment of Use: Hospitals, ICU, sub-acute care institutions and home.

REF	Name	Class	GMDN code
7740	Freevent DualCare Set 22	I	36071
7741	Freevent DualCare Set 15	I	36071
7744	Freevent DualCare Speaking Valve	I	36071
7745	Removal Aid	I	58705
7746	Freevent Connection strap	I	36071
7755	Freevent DualCare Speaking Valve Blue	I	36071

Intended Use:
Freevent HME 15 is a Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a ISO 15 mm connector. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance. The Freevent HME 15 Regular offers high airflow while Freevent HME 15 XtraMoist offers high humidification.

The HME is used in combination with Freevent DualCare Speaking valve/Freevent DualCare Speaking Valve Blue, with Freevent HME DigiTop/Freevent HME DigiTop Blue, or with HME DigiTop O2.

The HME is for single use, i.e. it has to be exchanged at least every 24 hours

REF	Name	Class	GMDN code
7742	Freevent HME 15 Regular (30pcs)	I	36071

Intended Use:
Freevent HME 22 Regular is a Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a Ø22mm connector. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance.

The HME is used in combination with Freevent DualCare Speaking Valve/Freevent DualCare Speaking Valve Blue, with Freevent HME DigiTop/Freevent HME DigiTop Blue, or with HME DigiTop O2.

The HME is for single use, i.e. it has to be exchanged at least every 24 hours

REF	Name	Class	GMDN code
7747	Freevent HME 22 Regular (30pcs)	I	36071

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

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This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Freevent® Neckband

Basic UDI: 7331791-GEN-A-000-0000-E6

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
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.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-GEN-A-000-0000-E6

REF	Name	Class	GMDN code
1651	Freevent Neckband, one-piece, small	I	63438
1652	Freevent Neckband, two-piece, small	I	63438
1661	Freevent Neckband, one-piece, large	I	63438
1662	Freevent Neckband, two-piece, large	I	63438
1751	Freevent Neckband, one-piece, small	I	63438
1752	Freevent Neckband, two-piece, small	I	63438
1761	Freevent Neckband, one-piece, large	I	63438
1762	Freevent Neckband, two-piece, large	I	63438

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

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Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-05 - 09:57

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Freevent® Tracheal Tube Cleansing Jar

Basic UDI: 7331791-TTU-A-000-0001-WK

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
The Freevent Tracheal Tube Cleansing Jar is intended for cleaning of all types of tracheal tubes with Freevent Tracheal Tube Detergent Powder.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-TTU-A-000-0001-WK

REF	Name	Class	GMDN code
1602	Freevent Tracheal Tube Cleansing Jar	I	62628

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

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Approved:	OP	Martin Richardson - MARRIC	2020-06-05 - 09:36
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-05 - 09:57

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Freevent® TubeBrush

Basic UDI: 7331791-GEN-A-000-0001-E9

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
The Freevent TubeBrush is used for cleaning of tracheostomy tubes ex situ.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
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Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-GEN-A-000-0001-E9

REF	Name	Class	GMDN code
1205	Freevent TubeBrush Sz 6	I	34883
1206	Freevent TubeBrush Sz 8	I	34883
1207	Freevent TubeBrush Sz 10	I	34883
1208	Freevent TubeBrush Sz 12	I	34883
1209	Freevent TubeBrush Sz 14	I	34883
1210	Freevent TubeBrush Set 1x8, 1x10, 1x12mm	I	34883

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

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Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-05 - 09:40

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Freevent® XtraCare™

Basic UDI: 7331791-HME-0-000-0004-XM

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
Freevent XtraCare is a single use Heat and Moisture Exchanger with electrostatic filter (HMEF) that conditions and filters inhaled air in patients spontaneously breathing through a tracheostoma.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-HME-0-000-0004-XM

REF	Name	Class	GMDN code
7767	Freevent XtraCare White	I	58705
7768	Freevent XtraCare Blue	I	58705
7788	Freevent XtraCare Blue	I	58705
7789	Freevent XtraCare White	I	58705

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.