DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® Clothing Stoma Cover

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

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

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 on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-TEX-0-000-0000-WK

REF	Device 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

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-TEX-0-000-0000-WK

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)

- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Number: VV-0544270 Status: Approved Version: 2.0
Name: DoC Freevent Clothing Stoma Cover 7331791-TEX-0-000-0000-WK

Document Approvals

Approved Date: 2023-09-08

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 08-Sep-2023 05:58:02 GMT+0000

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 08-Sep-2023 06:03:46 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® Dressing

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

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

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

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-COM-0-000-0001-52

REF	Device name	Class*	GMDN code
1425	Freevent Dressing AL 80x100	I	15624
14250	Freevent Dressing slt 90x100	I	15624
14251	Freevent Dressing AL slt 80x100	I	15624
14253	Freevent Dressing Combi slt 90x100	I	15624
14254	Freevent Dressing Combi AL slt 90x100	I	15624
14255	Freevent Dressing Combi 90x100	I	15624
14256	Freevent Dressing Combi AL 90x100	I	15624
14257	Freevent Dressing Combi slt 90x150	I	15624
14258	Freevent Dressing Combi AL slt 90x150	I	15624
14259	Freevent Dressing Combi 90x150	I	15624
142510	Freevent Dressing Dbl 90x100	I	15624
142511	Freevent Dressing Dbl AL 90x100	I	15624
142512	Freevent Dressing Dbl slt 90x100	I	15624
142513	Freevent Dressing Dbl AL slt 90x100	I	15624
142514	Freevent Dressing Dbl 90x150	I	15624
142515	Freevent Dressing Dbl AL slt 90x150	I	15624
142516	Freevent Dressing Dbl slt 90x150	I	15624
1425921	Freevent Trach Dressing slt 90x100	I	15624
1425923	Freevent Trach Dressing slt 90x150	I	15624
1425932	Freevent Dressing AL slt 90x100	I	15624
1425933	Freevent Dressing AL slt 90x150	I	15624
14250-PED	Freevent Dressing slt 65x70 PED	I	15624
142512-PED	Freevent Dressing Dbl slt 65x70	I	15624
14251-PED	Freevent Dressing AL slt 65x70	I	15624
14253H	Freevent Dressing Combi BG slt 90x100	I	15624
14253H-PED	Freevent Dressing Combi BG slt 65x70	I	15624
14253-PED	Freevent Dressing Combi slt 65x70	I	15624
14255H	Freevent Dressing Combi BG 90x100	I	15624
14256H	Freevent Dressing Combi AL/BG 90x100	I	15624
14259H	Freevent Dressing Combi BG slt 90x150	I	15624
18008-001	Freevent Dressing AL 65x70 PED	I	15624

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Approvals

Approved Date: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:37:03 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:51:02 GMT+0000

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:58:28 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® Dressing Pad

Basic UDI: 7331791-COM-0-000-0004-5B

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

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

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-COM-0-000-0004-5B

REF	Device name	Class*	GMDN code
142700-D	Freevent Dressing Pad slt 90x100	I	15624
142700-PED	Freevent Dressing Pad slt 65x70 PED	I	15624
142800	Freevent Dressing Pad 65x45	I	15624
1431	Freevent Dressing Foam 65x70	I	15624

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Approvals

Approved Date: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:35:09 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:49:48 GMT+0000

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:57:02 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® DualCare™

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

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:
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.

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-HME-0-000-0005-XQ

REF	Device 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

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Approvals
Approved Date: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:31:38 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:47:30 GMT+0000

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:43:36 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® HME 15

Basic UDI: 7331791-HME-0-000-0010-XE

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:
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 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.

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-HME-0-000-0010-XE

REF	Device name	Class*	GMDN code
7742	Freevent HME 15 Regular (30pcs)	I	58705

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Number: VV-0570833 Status: Approved Version: 1.0
Name: DoC Freevent HME 15 7331791-HME-0-000-0010-XE

Document Approvals

Approved Date: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:31:51 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:47:42 GMT+0000

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:45:16 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® HME 22

Basic UDI: 7331791-HME-0-000-0011-XH

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:
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.

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-HME-0-000-0011-XH

REF	Device name	Class*	GMDN code
7747	Freevent HME 22 Regular (30pcs)	I	58705

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Number: VV-0570834 Status: Approved Version: 1.0
Name: DoC Freevent HME 22 7331791-HME-0-000-0011-XH

Document Approvals
Approved Date: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:32:08 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:47:59 GMT+0000

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:45:56 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® Neckband

Basic UDI: 7331791-GEN-A-000-0005-EM

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:
Freevent Neckband is used for holding a tube or button that connects to the trachea in place. It is a single use device intended for adult and pediatric patients. Not for neonatal use.

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-GEN-A-000-0005-EM

REF	Device 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

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Number: VV-0570638 Status: Approved Version: 1.0
Name: DoC Freevent Neckband 7331791-GEN-A-000-0005-EM

Document Approvals

Approved Date: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:34:51 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:49:33 GMT+0000

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:56:02 GMT+0000

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 09:53
Reviewed:	QA	John Wennborg - JOHWEN	2021-05-19 - 11:04
Approved:	OP	Martin Richardson - MARRIC	2021-05-19 - 11:53
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 17:04

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

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: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 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

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.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® TubeBrush

Basic UDI: 7331791-GEN-A-000-0006-EQ

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

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

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-GEN-A-000-0006-EQ

REF	Device 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

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Number: VV-0570832 Status: Approved Version: 1.0
Name: DoC Freevent TubeBrush 7331791-GEN-A-000-0006-EQ

Document Approvals

Approved Date: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:33:56 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:48:45 GMT+0000

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:53:20 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® XtraCare™

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

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

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

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

Document Number: VV-0544265 Status: Approved Version: 2.0
Name: DoC Freevent XtraCare 7331791-HME-0-000-0004-XM

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-HME-0-000-0004-XM

REF	Device 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
8004	Freevent XtraCare Mini White 30 pcs	I	58705
8005	Freevent XtraCare Mini Blue 30 pcs	I	58705
8006	Freevent XtraCare Mini Pink 30 pcs	I	58705
8008	Freevent XtraCare Mini White 5 pcs	I	58705

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Number: VV-0544265 Status: Approved Version: 2.0
Name: DoC Freevent XtraCare 7331791-HME-0-000-0004-XM

Document Approvals

Approved Date: 2023-11-07

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 07-Nov-2023 08:36:55 GMT+0000

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Regulatory 07-Nov-2023 10:46:34 GMT+0000

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 Trach Accessories

REF	Name	Class	GMDN code
1502	Stoma Oil 100ml	IIb	57897
7756	HME DigiTop O2	IIa	58705
7769	Freevent O2 Adaptor 10pcs	IIa	58705
8007	Freevent O2 Adaptor Mini 10 pcs	IIa	58705
8034	Freevent Dressing Softfoam L	Is	15624
8035	Freevent Dressing Softfoam S	Is	15624
8036	Freevent Dressing Softfoam Slim L	Is	15624

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. 41310296-04

Competent Authority: *Medical Products Agency, Sweden*

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Document Approvals

Approved Date: 2023-11-07

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 07-Nov-2023 08:37:31 GMT+0000

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Regulatory 07-Nov-2023 10:46:50 GMT+0000

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 Trach-HME Products

REF	Name	Class	GMDN code
7704	TrachPhone (50 pcs)	IIa	58705
7705	MEDIFLUX HCH F6 (Medival)	IIa	58705
7707	TrachPhone (30 pcs)	IIa	58705
7723	TrachPhone (5 pcs)	IIa	58705

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. 41310296-04

Competent Authority: *Medical Products Agency, Sweden*

Atos Medical AB
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Document Approvals

Approved Date: 2023-09-08

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 08-Sep-2023 05:58:24 GMT+0000

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 08-Sep-2023 06:03:27 GMT+0000