| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|---|---|---|---|
| Issued: | QA | Ulrika Svensson - SEHRBHNU | 2021-05-19 - 09:46 |
| Reviewed: | QA | John Wennborg - JOHWEN | 2021-05-19 - 10:59 |
| Approved: | OP | Martin Richardson - MARRIC | 2021-05-19 - 11:54 |
| Released: | QA | Ulrika Svensson - SEHRBHNU | 2021-05-19 - 17:03 |

This document has been electronically signed by the persons above.

# DECLARATION OF CONFORMITY

## Provox® 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: 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

Released
Document No: 10000043843 Edition: 02 Release date: 2021-05-19

# DECLARATION OF CONFORMITY

## 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): |
|---|---|---|---|
| Issued: | QA | Karolina Nilsson - KARNIL | 2022-01-04 - 09:39 |
| Reviewed: | QA | Karolina Nilsson - KARNIL | 2022-01-04 - 12:56 |
| Approved: | OP | Martin Richardson - MARRIC | 2022-01-04 - 13:25 |
| Released: | QA | Karolina Nilsson - KARNIL | 2022-01-04 - 14:14 |

This document has been electronically signed by the persons above.

# DECLARATION OF CONFORMITY

## 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: 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

Document No: 10000043844 Edition: 06 Release date: 2022-01-04

# DECLARATION OF CONFORMITY

## 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 | 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 |

**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 | 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 |

**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): |
|---|---|---|---|
| Issued: | QA | Elin Algotson - ELIALG | 2021-12-28 - 10:49 |
| Reviewed: | QA | John Wennborg - JOHWEN | 2021-12-28 - 11:05 |
| Approved: | OP | Martin Richardson - MARRIC | 2021-12-28 - 16:11 |
| Released: | QA | Elin Algotson - ELIALG | 2021-12-28 - 16:34 |

This document has been electronically signed by the persons above.

# DECLARATION OF CONFORMITY

## 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: 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

Released
Document No: 10000043845 Edition: 04 Release date: 2021-12-28

# DECLARATION OF CONFORMITY

## 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 | 58705 |

**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 | 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.

| 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

Document No: 10000043840 Edition: 02 Release date: 2021-05-19

Released

# 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.

| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|---|---|---|---|
| Issued: | QA | Ulrika Svensson - SEHRBHNU | 2021-05-19 - 09:54 |
| Reviewed: | QA | John Wennborg - JOHWEN | 2021-05-19 - 11:06 |
| Approved: | OP | Martin Richardson - MARRIC | 2021-05-19 - 11:53 |
| Released: | QA | Ulrika Svensson - SEHRBHNU | 2021-05-19 - 17:05 |

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 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 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, 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

Document No: 10000043829 Edition: 04 Release date: 2021-05-19

Released

# 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 |
| 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 |

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.

Atos
atosmedical.com

*Document title*
Declaration of Conformity

| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|---|---|---|---|
| Issued: | QA | Ulrika Svensson - SEHRBHNU | 2021-05-21 - 07:44 |
| Reviewed: | QA | John Wennborg - JOHWEN | 2021-05-21 - 08:52 |
| Approved: | OP | Martin Richardson - MARRIC | 2021-05-21 - 09:31 |
| Released: | QA | Ulrika Svensson - SEHRBHNU | 2021-05-25 - 13:37 |

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 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 |
| 8038 | Freevent Dressing Coated L | Is | 15624 |
| 8039 | Freevent Dressing Coated M | 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*

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
E-mail: info@atosmedical.com



Document No: 10000043842 Edition: 04 Release date: 2021-05-25

Atos
atosmedical.com

*Document title*
Declaration of Conformity

| Justification: | Function: | Electronic signature justification: | Signed: Date (yyyy-mm-dd) - Time (hh:mm): |
|---|---|---|---|
| Issued: | QA | Ulrika Svensson - SEHRBHNU | 2021-07-14 - 11:46 |
| Reviewed: | QA | John Wennborg - JOHWEN | 2021-07-14 - 12:26 |
| Approved: | OP | Martin Richardson - MARRIC | 2021-07-14 - 14:51 |
| Released: | QA | Ulrika Svensson - SEHRBHNU | 2021-07-14 - 14:59 |

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 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
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
E-mail: info@atosmedical.com



Document No: 10000030112 Edition: 07 Release date: 2021-07-14