Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 16:53

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Freevent® Neckband, Provox® TubeHolder

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:
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: 10000043841 Edition: 03 Release date: 2021-05-19

DECLARATION OF CONFORMITY

7331791-GEN-A-000-0000-E6

Intended Use:
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.

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

Intended Use:
The Provox TubeHolder is used for extra support for Provox LaryButton and Provox LaryTube. It goes around the neck of the user and the ends are attached to the "ears" of the LaryTube/LaryButton. The TubeHolder is adjustable in length using a Velcro® connection and allows the user to cut the band to suitable length.

REF	Name	Class	GMDN code
7668	Provox TubeHolder	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.

Released
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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 16:53

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Freevent® TubeBrush, Provox® 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:
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
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DECLARATION OF CONFORMITY

7331791-GEN-A-000-0001-E9

Intended Use:
The Freevent TubeBrush is used for cleaning of tracheostomy tubes ex situ.

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

Intended Use:
The Provox TubeBrush is used for cleaning of the Provox LaryTube and Provox LaryButton ex situ.

REF	Name	Class	GMDN code
7660	Provox TubeBrush 8 mm	I	34883
7661	Provox TubeBrush 12 mm	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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This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® FenestrationPunch

Basic UDI: 7331791-LTU-A-000-0000-JQ

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 Fenestration Punch is used for making small fenestrations in a Provox LaryTube at desired locations.

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

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DECLARATION OF CONFORMITY

7331791-LTU-A-000-0000-JQ

REF	Name	Class	GMDN code
7654	Provox FenestrationPunch	I	38792

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	2021-05-27 - 13:08

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 Provox Lary Products

REF	Name	Class	GMDN code
7601	Provox LaryTube 8/27	IIb	38792
7602	Provox LaryTube 8/36	IIb	38792
7603	Provox LaryTube 8/55	IIb	38792
7605	Provox LaryTube 9/27	IIb	38792
7606	Provox LaryTube 9/36	IIb	38792
7607	Provox LaryTube 9/55	IIb	38792
7609	Provox LaryTube 10/27	IIb	38792
7610	Provox LaryTube 10/36	IIb	38792
7611	Provox LaryTube 10/55	IIb	38792
7613	Provox LaryTube 12/27	IIb	38792
7614	Provox LaryTube 12/36	IIb	38792
7615	Provox LaryTube 12/55	IIb	38792
7624	Provox LaryTube 8/36 with Ring	IIb	38792
7625	Provox LaryTube 8/55 with Ring	IIb	38792
7626	Provox LaryTube 9/36 with Ring	IIb	38792
7627	Provox LaryTube 9/55 with Ring	IIb	38792
7628	Provox LaryTube 10/36 with Ring	IIb	38792
7629	Provox LaryTube 10/55 with Ring	IIb	38792
7630	Provox LaryTube 12/36 with Ring	IIb	38792
7631	Provox LaryTube 12/55 with Ring	IIb	38792
7637	Provox LaryTube 8/36, Fenestrated	IIb	38792
7638	Provox LaryTube 8/55, Fenestrated	IIb	38792
7640	Provox LaryTube 9/36, Fenestrated	IIb	38792
7641	Provox LaryTube 9/55, Fenestrated	IIb	38792
7643	Provox LaryTube 10/36, Fenestrated	IIb	38792
7644	Provox LaryTube 10/55, Fenestrated	IIb	38792
7646	Provox LaryTube 12/36, Fenestrated	IIb	38792

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7647	Provox LaryTube 12/55, Fenestrated	IIb	38792
7601FR	Provox LaryTube 8/27	IIb	38792
7602FR	Provox LaryTube 8/36	IIb	38792
7603FR	Provox LaryTube 8/55	IIb	38792
7605FR	Provox LaryTube 9/27	IIb	38792
7606FR	Provox LaryTube 9/36	IIb	38792
7607FR	Provox LaryTube 9/55	IIb	38792
7609FR	Provox LaryTube 10/27	IIb	38792
7610FR	Provox LaryTube 10/36	IIb	38792
7611FR	Provox LaryTube 10/55	IIb	38792
7613FR	Provox LaryTube 12/27	IIb	38792
7614FR	Provox LaryTube 12/36	IIb	38792
7615FR	Provox LaryTube 12/55	IIb	38792
7624FR	Provox LaryTube 8/36 with Ring	IIb	38792
7625FR	Provox LaryTube 8/55 with Ring	IIb	38792
7626FR	Provox LaryTube 9/36 with Ring	IIb	38792
7627FR	Provox LaryTube 9/55 with Ring	IIb	38792
7628FR	Provox LaryTube 10/36 with Ring	IIb	38792
7629FR	Provox LaryTube 10/55 with Ring	IIb	38792
7630FR	Provox LaryTube 12/36 with Ring	IIb	38792
7631FR	Provox LaryTube 12/55 with Ring	IIb	38792
7637FR	Provox LaryTube 8/36, Fenestrated	IIb	38792
7638FR	Provox LaryTube 8/55, Fenestrated	IIb	38792
7640FR	Provox LaryTube 9/36, Fenestrated	IIb	38792
7641FR	Provox LaryTube 9/55, Fenestrated	IIb	38792
7643FR	Provox LaryTube 10/36, Fenestrated	IIb	38792
7644FR	Provox LaryTube 10/55, Fenestrated	IIb	38792
7646FR	Provox LaryTube 12/36, Fenestrated	IIb	38792
7647FR	Provox LaryTube 12/55, Fenestrated	IIb	38792
7648	Provox LaryTube Sizer Kit	IIa	38792
7671	Provox LaryButton 12/8	IIb	14093
7672	Provox LaryButton 14/8	IIb	14093
7673	Provox LaryButton 16/8	IIb	14093
7674	Provox LaryButton 18/8	IIb	14093
7685	Provox LaryButton 12/18	IIb	14093
7686	Provox LaryButton 14/18	IIb	14093
7687	Provox LaryButton 16/18	IIb	14093
7688	Provox LaryButton 18/18	IIb	14093
7690	Provox LaryButton Sizer Kit	IIa	14093

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The Provox Life Lary Products

REF	Name	Class	GMDN code
7409	Provox Life LaryTube 8/27 Standard	IIb	38792
7410	Provox Life LaryTube 8/36 Standard	IIb	38792
7411	Provox Life LaryTube 8/55 Standard	IIb	38792
7412	Provox Life LaryTube 9/27 Standard	IIb	38792
7413	Provox Life LaryTube 9/36 Standard	IIb	38792
7414	Provox Life LaryTube 9/55 Standard	IIb	38792
7415	Provox Life LaryTube 10/27 Standard	IIb	38792
7416	Provox Life LaryTube 10/36 Standard	IIb	38792
7417	Provox Life LaryTube 10/55 Standard	IIb	38792
7418	Provox Life LaryTube 12/27 Standard	IIb	38792
7419	Provox Life LaryTube 12/36 Standard	IIb	38792
7420	Provox Life LaryTube 12/55 Standard	IIb	38792
7421	Provox Life LaryTube 8/36 Standard with Ring	IIb	38792
7422	Provox Life LaryTube 8/55 Standard with Ring	IIb	38792
7423	Provox Life LaryTube 9/36 Standard with Ring	IIb	38792
7424	Provox Life LaryTube 9/55 Standard with Ring	IIb	38792
7425	Provox Life LaryTube 10/36 Standard with Ring	IIb	38792
7426	Provox Life LaryTube 10/55 Standard with Ring	IIb	38792
7427	Provox Life LaryTube 12/36 Standard with Ring	IIb	38792
7428	Provox Life LaryTube 12/55 Standard with Ring	IIb	38792
7429	Provox Life LaryTube 8/36, Fenestrated	IIb	38792
7430	Provox Life LaryTube 8/55, Fenestrated	IIb	38792
7431	Provox Life LaryTube 9/36, Fenestrated	IIb	38792
7432	Provox Life LaryTube 9/55, Fenestrated	IIb	38792
7433	Provox Life LaryTube 10/36, Fenestrated	IIb	38792
7434	Provox Life LaryTube 10/55, Fenestrated	IIb	38792
7435	Provox Life LaryTube 12/36, Fenestrated	IIb	38792
7436	Provox Life LaryTube 12/55, Fenestrated	IIb	38792
8040	Provox Life LaryButton 12/8	IIb	14093
8041	Provox Life LaryButton 12/18	IIb	14093
8042	Provox Life LaryButton 14/8	IIb	14093
8043	Provox Life LaryButton 14/18	IIb	14093
8044	Provox Life LaryButton 16/8	IIb	14093
8045	Provox Life LaryButton 16/18	IIb	14093
8046	Provox Life LaryButton 18/8	IIb	14093
8047	Provox Life LaryButton 18/18	IIb	14093
8048	Provox Life LaryTube 8/36 Fenestrated with Ring	IIb	38792
8049	Provox Life LaryTube 8/55 Fenestrated with Ring	IIb	38792
8050	Provox Life LaryTube 9/36 Fenestrated with Ring	IIb	38792
8051	Provox Life LaryTube 9/55 Fenestrated with Ring	IIb	38792
8052	Provox Life LaryTube 10/36 Fenestrated with Ring	IIb	38792
8053	Provox Life LaryTube 10/55 Fenestrated with Ring	IIb	38792

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Document title
Declaration of Conformity

8054	Provox Life LaryTube 12/36 Fenestrated with Ring	IIb	38792
8055	Provox Life LaryTube 12/55 Fenestrated with Ring	IIb	38792

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.

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Notified Body: *Intertek Semko AB, Sweden. Identification no. 0413*
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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

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Approved:	OP	Martin Richardson - MARRIC	2021-06-01 - 13:24
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-06-01 - 14:44

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® LaryClip, Stoma Sizing Guide

Basic UDI: 7331791-LTU-A-000-0001-JT

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: 1000004781 7 Edition: 01 Release date: 2021-06-01

Released

DECLARATION OF CONFORMITY

7331791-LTU-A-000-0001-JT

Intended Use:
The Provox LaryClip is used for extra support for LaryButton and LaryTube.
The product consists of two parts, one that is attached to the patients' skin on each side of the stoma and the other part is attached to the LaryButton or the LaryTube. The two parts are then connected by Velcro.

REF	Name	Class	GMDN code
7669	Provox LaryClip	I	35752

Intended Use:
Stoma Sizing Guide is a single use device intended to help the prescribing clinician determine which size of LaryTube or LaryButton in the Provox and Provox Life range respectively should be prescribed to the patient. Stoma Sizing Guide is intended to be used by a prescribing clinician who has read the IFU for Provox and Provox Life LaryTube and LaryButton respectively.
Stoma Sizing Guide can also be used by patients to monitor the stoma size.

REF	Name	Class	GMDN code
7135	Stoma Sizing Guide	I	TBD

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	2021-05-19 - 11:56
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 16:54

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Swab

Basic UDI: 7331791-GEN-A-000-0002-EC

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:
Provox Swab is a single use swab for ex-situ cleaning of Provox LaryTube, Provox LaryButton and tracheostomy inner tubes.

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-GEN-A-000-0002-EC

REF	Name	Class	GMDN code
8250	Provox Swab Small	I	62956
8251	Provox Swab Medium	I	62956
8252	Provox Swab Large	I	62956
8258	Provox Swab XtraLarge	I	62956

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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