DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent® Neckband, Provox® TubeHolder

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

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:
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 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-000-0000-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	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

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	Device name	Class*	GMDN code
7668	Provox TubeHolder	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 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 05:57:07 GMT+0000

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

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Approved:	OP	Martin Richardson - MARRIC	2023-02-21 - 19:16
Released:	QA	Ulrika Svensson - SEHRBHNU	2023-02-22 - 08:17

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

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, any other applicable Union legislation and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and, UK Medical Devices Regulations 2002, including amendments in effect at the issuance date.

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, SE-242 35 Hörby
Sweden

Telephone: +46 (0)415 198 00
Email: Info@atosmedical.com
Web: www.atosmedical.com

SRN number: **SE-MF-000000725**

Competent Authority **Medical Products Agency**
Sweden

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-GEN-A-000-0001-E9

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

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

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

REF	Device 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.

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

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 09:07
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Approved:	OP	Martin Richardson - MARRIC	2021-05-19 - 11:57
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 16:54

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

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.

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
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

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
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.

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: 2023-09-07

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 06-Sep-2023 11:25:10 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 07-Sep-2023 12:40:29 GMT+0000

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Approved:	OP	Martin Richardson - MARRIC	2023-06-07 - 08:33
Released:			

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® LaryClip

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, any other applicable Union legislation and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and, UK Medical Devices Regulations 2002, including amendments in effect at the issuance date.

Intended use/purpose:
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.

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, SE-242 35 Hörby
Sweden

Telephone: +46 (0)415 198 00
Email: Info@atosmedical.com
Web: www.atosmedical.com

SRN number: **SE-MF-000000725**

Competent Authority **Medical Products Agency**
Sweden

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-LTU-A-000-0001-JT

REF	Device name	Class	GMDN code
7669	Provox LaryClip	I	35752

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

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Swab

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

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:
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 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-000-0002-EC

REF	Device 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

*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:
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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: 2023-09-08

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 08-Sep-2023 06:18:52 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 08-Sep-2023 06:21:59 GMT+0000

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2023-05-09 - 11:52
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Approved:	OP	Martin Richardson - MARRIC	2023-06-07 - 08:33
Released:	QA	Ulrika Svensson - SEHRBHNU	2023-06-07 - 09:15

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Stoma Sizing Guide

Basic UDI: 7331791-LTU-0-000-0006-3S

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, any other applicable Union legislation and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and, UK Medical Devices Regulations 2002, including amendments in effect at the issuance date.

Intended use/purpose:
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.

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**
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Telephone: +46 (0)415 198 00
Email: Info@atosmedical.com
Web: www.atosmedical.com

SRN number: **SE-MF-000000725**

Competent Authority **Medical Products Agency**
Sweden

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-LTU-0-000-0006-3S

REF	Device name	Class	GMDN code
7135	Stoma Sizing Guide	I	65811

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
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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