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	12292
7602	Provox LaryTube 8/36	IIb	12292
7603	Provox LaryTube 8/55	IIb	12292
7605	Provox LaryTube 9/27	IIb	12292
7606	Provox LaryTube 9/36	IIb	12292
7607	Provox LaryTube 9/55	IIb	12292
7609	Provox LaryTube 10/27	IIb	12292
7610	Provox LaryTube 10/36	IIb	12292
7611	Provox LaryTube 10/55	IIb	12292
7613	Provox LaryTube 12/27	IIb	12292
7614	Provox LaryTube 12/36	IIb	12292
7615	Provox LaryTube 12/55	IIb	12292
7624	Provox LaryTube 8/36 with Ring	IIb	12292
7625	Provox LaryTube 8/55 with Ring	IIb	12292
7626	Provox LaryTube 9/36 with Ring	IIb	12292
7627	Provox LaryTube 9/55 with Ring	IIb	12292
7628	Provox LaryTube 10/36 with Ring	IIb	12292
7629	Provox LaryTube 10/55 with Ring	IIb	12292
7630	Provox LaryTube 12/36 with Ring	IIb	12292
7631	Provox LaryTube 12/55 with Ring	IIb	12292
7637	Provox LaryTube 8/36, Fenestrated	IIb	12292
7638	Provox LaryTube 8/55, Fenestrated	IIb	12292
7640	Provox LaryTube 9/36, Fenestrated	IIb	12292
7641	Provox LaryTube 9/55, Fenestrated	IIb	12292
7643	Provox LaryTube 10/36, Fenestrated	IIb	12292
7644	Provox LaryTube 10/55, Fenestrated	IIb	12292
7646	Provox LaryTube 12/36, Fenestrated	IIb	12292
7647	Provox LaryTube 12/55, Fenestrated	IIb	12292
7601FR	Provox LaryTube 8/27	IIb	12292
7602FR	Provox LaryTube 8/36	IIb	12292
7603FR	Provox LaryTube 8/55	IIb	12292
7605FR	Provox LaryTube 9/27	IIb	12292
7606FR	Provox LaryTube 9/36	IIb	12292
7607FR	Provox LaryTube 9/55	IIb	12292
7609FR	Provox LaryTube 10/27	IIb	12292
7610FR	Provox LaryTube 10/36	IIb	12292

7611FR	Provox LaryTube 10/55	IIb	12292
7613FR	Provox LaryTube 12/27	IIb	12292
7614FR	Provox LaryTube 12/36	IIb	12292
7615FR	Provox LaryTube 12/55	IIb	12292
7624FR	Provox LaryTube 8/36 with Ring	IIb	12292
7625FR	Provox LaryTube 8/55 with Ring	IIb	12292
7626FR	Provox LaryTube 9/36 with Ring	IIb	12292
7627FR	Provox LaryTube 9/55 with Ring	IIb	12292
7628FR	Provox LaryTube 10/36 with Ring	IIb	12292
7629FR	Provox LaryTube 10/55 with Ring	IIb	12292
7630FR	Provox LaryTube 12/36 with Ring	IIb	12292
7631FR	Provox LaryTube 12/55 with Ring	IIb	12292
7637FR	Provox LaryTube 8/36, Fenestrated	IIb	12292
7638FR	Provox LaryTube 8/55, Fenestrated	IIb	12292
7640FR	Provox LaryTube 9/36, Fenestrated	IIb	12292
7641FR	Provox LaryTube 9/55, Fenestrated	IIb	12292
7643FR	Provox LaryTube 10/36, Fenestrated	IIb	12292
7644FR	Provox LaryTube 10/55, Fenestrated	IIb	12292
7646FR	Provox LaryTube 12/36, Fenestrated	IIb	12292
7647FR	Provox LaryTube 12/55, Fenestrated	IIb	12292
7648	Provox LaryTube Sizer Kit	IIa	12292
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	12292
7410	Provox Life LaryTube 8/36 Standard	IIb	12292
7411	Provox Life LaryTube 8/55 Standard	IIb	12292
7412	Provox Life LaryTube 9/27 Standard	IIb	12292
7413	Provox Life LaryTube 9/36 Standard	IIb	12292
7414	Provox Life LaryTube 9/55 Standard	IIb	12292
7415	Provox Life LaryTube 10/27 Standard	IIb	12292
7416	Provox Life LaryTube 10/36 Standard	IIb	12292
7417	Provox Life LaryTube 10/55 Standard	IIb	12292
7418	Provox Life LaryTube 12/27 Standard	IIb	12292

7419	Provox Life LaryTube 12/36 Standard	IIb	12292
7420	Provox Life LaryTube 12/55 Standard	IIb	12292
7421	Provox Life LaryTube 8/36 Standard with Ring	IIb	12292
7422	Provox Life LaryTube 8/55 Standard with Ring	IIb	12292
7423	Provox Life LaryTube 9/36 Standard with Ring	IIb	12292
7424	Provox Life LaryTube 9/55 Standard with Ring	IIb	12292
7425	Provox Life LaryTube 10/36 Standard with Ring	IIb	12292
7426	Provox Life LaryTube 10/55 Standard with Ring	IIb	12292
7427	Provox Life LaryTube 12/36 Standard with Ring	IIb	12292
7428	Provox Life LaryTube 12/55 Standard with Ring	IIb	12292
7429	Provox Life LaryTube 8/36, Fenestrated	IIb	12292
7430	Provox Life LaryTube 8/55, Fenestrated	IIb	12292
7431	Provox Life LaryTube 9/36, Fenestrated	IIb	12292
7432	Provox Life LaryTube 9/55, Fenestrated	IIb	12292
7433	Provox Life LaryTube 10/36, Fenestrated	IIb	12292
7434	Provox Life LaryTube 10/55, Fenestrated	IIb	12292
7435	Provox Life LaryTube 12/36, Fenestrated	IIb	12292
7436	Provox Life LaryTube 12/55, Fenestrated	IIb	12292
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	12292
8049	Provox Life LaryTube 8/55 Fenestrated with Ring	IIb	12292
8050	Provox Life LaryTube 9/36 Fenestrated with Ring	IIb	12292
8051	Provox Life LaryTube 9/55 Fenestrated with Ring	IIb	12292
8052	Provox Life LaryTube 10/36 Fenestrated with Ring	IIb	12292
8053	Provox Life LaryTube 10/55 Fenestrated with Ring	IIb	12292
8054	Provox Life LaryTube 12/36 Fenestrated with Ring	IIb	12292
8055	Provox Life LaryTube 12/55 Fenestrated with Ring	IIb	12292

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: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:33:23 GMT+0000

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Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:52:15 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® LaryClip

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

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 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 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-LTU-A-000-0001-JT

REF	Device name	Class*	GMDN code
7669	Provox LaryClip	I	35752

*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-0544964 Status: Approved Version: 3.0
Name: DoC Provox LaryClip 7331791-LTU-A-000-0001-JT

Document Approvals

Approved Date: 2024-03-14

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Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 14-Mar-2024 06:33:05 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 14-Mar-2024 07:23:48 GMT+0000

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:
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

Document Approvals

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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

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® TubeBrush

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

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 Provox TubeBrush is a brush intended for ex-situ cleaning of the Provox LaryTube and Provox LaryButton.

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-0544266 Status: Approved Version: 2.0
Name: DoC Provox TubeBrush 7331791-GEN-A-000-0001-E9

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-GEN-A-000-0001-E9

REF	Device name	Class*	GMDN code
7660	Provox TubeBrush 8 mm	I	34883
7661	Provox TubeBrush 12 mm	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
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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 Number: VV-0544266 Status: Approved Version: 2.0
Name: DoC Provox TubeBrush 7331791-GEN-A-000-0001-E9

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Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:54:18 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

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:
Provox TubeHolder is intended to provide extra support for Provox LaryTube's and Provox LaryButton's range of devices. It goes around the neck of the user and is attached to the eyelets of LaryTube/LaryButton, and is adjustable in length.

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

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
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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-0544268 Status: Approved Version: 3.0
Name: DoC Provox TubeHolder 7331791-GEN-A-000-0000-E6

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DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Stoma Sizing Guide

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

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:
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 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-LTU-0-000-0006-3S

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

*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
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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

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