DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Life™ Adhesives

Basic UDI: 7331791-ADH-0-000-0001-CT

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 Life Adhesives are single use adhesives that provide attachment for Provox Life HMEs and accessories after total laryngectomy.

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-ADH-0-000-0001-CT

REF	Device name	Class*	GMDN code
7401	Provox Life FreeHands Adhesive	I	62175
7460	Provox Life Standard Adhesive Round	I	62175
7461	Provox Life Standard Adhesive Oval	I	62175
7462	Provox Life Standard Adhesive Plus	I	62175
7463	Provox Life Sensitive Adhesive Round	I	62175
7464	Provox Life Sensitive Adhesive Oval	I	62175
7465	Provox Life Sensitive Adhesive Oval B	I	62175
7466	Provox Life Sensitive Adhesive Plus	I	62175
8065	Provox Life Standard Experience Round	I	62175
8066	Provox Life Standard Experience Oval	I	62175
8067	Provox Life Standard Experience Plus	I	62175
8068	Provox Life Sensitive Experience Round	I	62175
8069	Provox Life Sensitive Experience Oval	I	62175
8070	Provox Life Sensitive Experience Plus	I	62175
8071	Provox Life Stability Experience	I	62175
8075	Provox Life Night Adhesive Experience	I	62175
8261	Provox Life Night Adhesive	I	62175
8263	Provox Life Stability Adhesive	I	62175

*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: 2023-12-12

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:29:48 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:46:29 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:55:40 GMT+0000

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Issued:	QA	Ulrika Svensson - SEHRBHNU	2023-02-21 - 13:20
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Approved:	OP	Martin Richardson - MARRIC	2023-02-22 - 17:49
Released:	QA	Ulrika Svensson - SEHRBHNU	2023-02-23 - 08:05

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Life™ BasePlate Adaptor

Basic UDI: 7331791-HME-A-000-0005-FB

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:
Provox Life BasePlate Adaptor is an accessory that allows attaching medical device, e.g. an HME, with an ISO 15 mm standard connector to a Provox Life attachment.

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-HME-A-000-0005-FB

REF	Device name	Class	GMDN code
8057	Provox Life BasePlate Adaptor	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.

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	2022-08-25 - 10:55
Reviewed:	QA	John Wennborg - JOHWEN	2022-08-26 - 07:54
Approved:	OP	Martin Richardson - MARRIC	2022-08-26 - 08:06
Released:	QA	Ulrika Svensson - SEHRBHNU	2022-08-26 - 08:12

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Life™ Experience Packs

Basic UDI: 7331791-KIT-0-000-0005-J3

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 Life HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma.

Provox Life Adhesives are single use adhesives that provide attachment for Provox Life HMEs and accessories after total laryngectomy.

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-KIT-0-000-0005-J3

REF	Name	Class	GMDN code
8060	Provox Life Day & Night Experience Round	I	58705
8061	Provox Life Day & Night Experience Oval	I	58705
8062	Provox Life Day & Night Experience Plus	I	58705
8063	Provox Life Day & Night EXP Sensitive	I	58705
8064	Provox Life Day & Night EXP Stability	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.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Life™ FreeHands HME®

Basic UDI: 7331791-HME-0-000-0008-XZ

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 Life FreeHands HME is a single use heat- and moisture exchanger intended for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and in combination with a Provox speaking valve.

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-0544784 Status: Approved Version: 2.0
Name: DoC Provox Life FreeHands HME 7331791-HME-0-000-0008-XZ

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-HME-0-000-0008-XZ

REF	Device name	Class*	GMDN code
7440	Provox Life FreeHands HME	I	58705
7477	Provox Life Sample Pack FreeHands HME	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-0544784 Status: Approved Version: 2.0
Name: DoC Provox Life FreeHands HME 7331791-HME-0-000-0008-XZ

Document Approvals

Approved Date: 2023-12-12

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Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:46:49 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:54:33 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Life™ HMEs

Basic UDI: 7331791-HME-0-000-0001-XC

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 Life HMEs are single use heat- and moisture exchangers for patients 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		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-HME-0-000-0001-XC

REF	Device name	Class*	GMDN code
7475	Provox Life Sample Pack Protect HME	I	58705
7476	Provox Life Sample Pack Energy HME	I	58705
8072	Provox Life Night HME Experience	I	58705
8073	Provox Life Energy HME Experience	I	58705
8074	Provox Life Protect HME Experience	I	58705
8262	Provox Life Night HME	I	58705
8264	Provox Life Home HME Experience	I	58705
8265	Provox Life Go HME Experience	I	58705
8310	Provox Life Go HME	I	58705
8311	Provox Life Home HME	I	58705
8312	Provox Life Energy HME	I	58705
8313	Provox Life Protect HME	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-0544318 Status: Approved Version: 2.0
Name: DoC Provox Life HMEs 7331791-HME-0-000-0001-XC

Document Approvals

Approved Date: 2023-09-20

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 19-Sep-2023 10:50:15 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 20-Sep-2023 06:32:08 GMT+0000

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2022-08-25 - 11:00
Reviewed:	QA	John Wennborg - JOHWEN	2022-08-26 - 07:55
Approved:	OP	Martin Richardson - MARRIC	2022-08-26 - 08:06
Released:	QA	Ulrika Svensson - SEHRBHNU	2022-08-26 - 08:12

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Life™ Sample Packs

Basic UDI: 7331791-KIT-0-000-0003-HV

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 Life HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma.

Provox Life Adhesives are single use adhesives that provide attachment for Provox Life HMEs and accessories after total laryngectomy.

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-KIT-0-000-0003-HV

REF	Name	Class	GMDN code
7467	Provox Life Sample Pack Standard Round	I	58705
7468	Provox Life Sample Pack Standard Oval	I	58705
7469	Provox Life Sample Pack Standard Plus	I	58705
7470	Provox Life Sample Pack Sensitive Round	I	58705
7471	Provox Life Sample Pack Sensitive Oval	I	58705
7472	Provox Life Sample Pack Sensitive Plus	I	58705
7473	Provox Life Sample Pack Stability	I	58705
7474	Provox Life Sample Pack Night	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.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Life™ Shower

Basic UDI: 7331791-ADH-A-000-0001-UB

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 Life Shower is a single patient use device intended to be placed into a Provox Life attachment to avoid water from entering the tracheostoma during showering.

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-ADH-A-000-0001-UB

REF	Device name	Class*	GMDN code
8308	Provox Life Shower	I	62047

*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-0544319 Status: Approved Version: 2.0
Name: DoC Provox Life Shower 7331791-ADH-A-000-0001-UB

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 05:58:36 GMT+0000

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 08-Sep-2023 06:04:04 GMT+0000