DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Adhesive Remover

Basic UDI: 7331791-ADH-A-000-0005-UP

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 Adhesive Remover is a single use wipe to help laryngectomized patients remove Provox Adhesives and Provox Silicone Glue.

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-000-0005-UP

REF	Device name	Class*	GMDN code
8012	Provox Adhesive Remover	I	60494

*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: 2023-09-07

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 07-Sep-2023 14:02:41 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 18:38:51 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Adhesive Strip

Basic UDI: 7331791-ADH-A-000-0002-UE

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 Adhesive Strip is a single use device to seal Provox adhesives, e.g. 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-000-0002-UE

REF	Device name	Class*	GMDN code
8015	Provox Adhesive Strip	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
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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

Approved Date: 2023-08-30

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 30-Aug-2023 08:48:01 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 30-Aug-2023 11:14:25 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Adhesives

Basic UDI: 7331791-ADH-0-000-0000-CQ

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 Adhesives are single use devices intended for laryngectomized patients breathing through a tracheostoma. The devices are attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.

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-0-000-0000-CQ

REF	Device name	Class*	GMDN code
7253	Provox Adhesive Flexiderm Round	I	62175
7253-18	Provox Adhesive Flexiderm Round	I	62175
7254	Provox Adhesive Flexiderm Oval	I	62175
7254-18	Provox Adhesive Flexiderm Oval	I	62175
7255	Provox Adhesive Optiderm Round	I	62175
7255-18	Provox Adhesive Optiderm Round	I	62175
7256	Provox Adhesive Optiderm Oval	I	62175
7256-18	Provox Adhesive Optiderm Oval	I	62175
7253ES	Provox Adhesive Flexiderm Round	I	62175
7254ES	Provox Adhesive Flexiderm Oval	I	62175
7254JP	Provox Adhesive Flexiderm Oval	I	62175
7256JP	Provox Adhesive Optiderm Oval	I	62175
7331	Provox Adhesive FlexiDerm Plus	I	62175
7331-18	Provox Adhesive FlexiDerm Plus	I	62175
7332	Provox Adhesive OptiDerm Plus	I	62175
7332-18	Provox Adhesive OptiDerm Plus	I	62175
7265	Provox XtraBase Adhesive	I	62175
7265-18	Provox XtraBase Adhesive	I	62175
8233	Provox XtraBase (3pcs)	I	62175
8234	Provox FlexiDerm Round (3pcs)	I	62175
8235	Provox FlexiDerm Oval (3pcs)	I	62175
8236	Provox Optiderm Round (3pcs)	I	62175
8237	Provox Optiderm Oval (3pcs)	I	62175
8238	Provox FlexiDerm Plus (3pcs)	I	62175
8239	Provox Optiderm Plus (3pcs)	I	62175
7289	Provox StabiliBase (15 pcs)	I	62175
7289-18	Provox StabiliBase (15 pcs)	I	62175
7299	Provox StabiliBase (3 pcs)	I	62175
7318	Provox StabiliBase OptiDerm (15pc)	I	62175
7328	Provox StabiliBase OptiDerm (3pcs)	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 Number: VV-0544274 Status: Approved Version: 3.0
Name: DoC Provox Adhesives 7331791-ADH-0-000-0000-CQ

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 18:38:04 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:52:00 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:38:51 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® BasePlate Adaptor

Basic UDI: 7331791-HME-A-000-0003-F5

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

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-A-000-0003-F5

REF	Device name	Class*	GMDN code
7263	Provox BasePlate Adaptor	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
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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

Approved Date: 2023-12-12

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:30:36 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:47:19 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:51:38 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Cleaning Towel

Basic UDI: 7331791-ADH-A-000-0003-UH

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 Cleaning Towel is intended for cleaning around the stoma, it will remove oil from the skin. They are intended to use before application of Provox Adhesives.

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-000-0003-UH

REF	Device name	Class*	GMDN code
7244	Provox Cleaning Towel 10-p	I	46205

*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

Document Approvals

Approved Date: 2023-09-07

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 07-Sep-2023 12:36:48 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 12:43:07 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® HME Cassette Adaptor

Basic UDI: 7331791-HME-A-000-0008-FL

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 HME Cassette Adaptor is intended to facilitate a connection between Provox HME Cassettes and on the market available tracheal cannulas with ISO-cone (15mm).

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-A-000-0008-FL

REF	Device name	Class*	GMDN code
7246	Provox HME Cassette Adaptor	I	63623

*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 Number: VV-0570632 Status: Approved Version: 1.0
Name: DoC Provox HME Cassette Adaptor 7331791-HME-A-000-0008-FL

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 18:30:20 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:47:01 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:53:01 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Luna® Adhesive

Basic UDI: 7331791-ADH-0-000-0002-CW

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 Luna Adhesive is a skin-friendly, single use adhesive that provides attachment for the Provox Luna HME for night-time use 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-0-000-0002-CW

REF	Device name	Class*	GMDN code
8014	Provox Luna 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
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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 Approvals

Approved Date: 2023-12-11

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:36:50 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:50:50 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Luna® ShowerAid™

Basic UDI: 7331791-ADH-A-000-0007-UV

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 Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma. Single patient use.

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-0570635 Status: Approved Version: 1.0
Name: DoC Provox Luna ShowerAid 7331791-ADH-A-000-0007-UV

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-ADH-A-000-0007-UV

REF	Device name	Class*	GMDN code
8016	Provox Luna ShowerAid	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
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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 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 18:37:51 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:51:50 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:40:01 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® ShowerAid™

Basic UDI: 7331791-ADH-A-000-0000-U8

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 ShowerAid (PF020) is used to temporarily replace the HME during showering. The ShowerAid can be placed in all Provox appliance holders.

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-000-0000-U8

REF	Device name	Class*	GMDN code
7260	Provox ShowerAid	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
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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 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 18:35:25 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 11-Dec-2023 19:49:59 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:50:28 GMT+0000

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2023-02-20 - 11:56
Reviewed:	QA	John Wennborg - JOHWEN	2023-02-20 - 21:09
Approved:	OP	Martin Richardson - MARRIC	2023-02-21 - 19:13
Released:	QA	Ulrika Svensson - SEHRBHNU	2023-02-22 - 08:19

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Silicone Glue

Basic UDI: 7331791-GEN-A-000-0003-EF

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:
To reinforce attachment of Provox Adhesive base plates to intact skin around 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: **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

Document No: 10000045946 Edition: 02 Release date: 2023-02-22

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-GEN-A-000-0003-EF

REF	Device name	Class	GMDN code
7720	Provox Silicone Glue	I	58978

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® Skin Barrier

Basic UDI: 7331791-ADH-A-000-0004-UL

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 Skin Barrier is a single use wipe for laryngectomized patients that forms a barrier between Provox Adhesive and the skin.

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-000-0004-UL

REF	Device name	Class*	GMDN code
8011	Provox Skin Barrier	I	58978

*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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Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 12-Dec-2023 09:44:47 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Tracheofix

Basic UDI: 7331791-COM-0-000-0003-58

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 Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic coverage of the 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-COM-0-000-0003-58

REF	Device name	Class*	GMDN code
1427	Provox Tracheofix 1 strip ivory 55x60	I	63378
1428	Provox Tracheofix 1 strip ivory 70x70	I	63378
1435	Provox Tracheofix 2 strips ivory 70x70	I	63378
1429H	Provox Tracheofix 1 strip beige 55x60	I	63378
1430H	Provox Tracheofix 1 strip beige 70x70	I	63378
1432H	Provox Tracheofix 2 strips beige 55x60	I	63378
1433H	Provox Tracheofix 2 strips beige 70x70	I	63378
1434H	Provox Tracheofix 1 strip beige 38x63	I	63378

*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

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Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:59:36 GMT+0000

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Wipes

Basic UDI: 7331791-ADH-A-000-0008-UY

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 Wipes is a combination of Provox Skin Barrier, Provox Adhesive Remover and Provox Cleaning Towel.

Provox Skin Barrier: Provox Skin Barrier is a single use wipe for laryngectomized patients that forms a barrier between Provox Adhesive and the skin.

Provox Adhesive Remover: Provox Adhesive Remover is a single use wipe to help laryngectomized patients remove Provox Adhesives and Provox Silicone Glue.

Provox Cleaning Towel: Provox Cleaning Towel is intended for cleaning around the stoma, it will remove oil from the skin. They are intended to be used before application of Provox Adhesives.

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-000-0008-UY

REF	Device name	Class*	GMDN code
8243	Provox Wipes	I	58978

*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

Document Number: VV-0570828 Status: Approved Version: 1.0
Name: DoC Provox Wipes 7331791-ADH-A-000-0008-UY

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