Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-18 - 16:27
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Approved:	OP	Martin Richardson - MARRIC	2021-05-18 - 17:27
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 11:42

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Adhesive Remover

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

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

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045923 Edition: 01 Release date: 2021-05-19

Released

DECLARATION OF CONFORMITY

7331791-ADH-A-000-0005-UP

REF	Name	Class	GMDN code
8012	Provox Adhesive Remover	I	60494

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.

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 15:46
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Approved:	OP	Martin Richardson - MARRIC	2021-05-19 - 17:38
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 20:50

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Adhesive Strip™

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

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 Adhesive Strip is a single use device to seal Provox adhesives, e.g. during showering.

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
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Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045924 Edition: 02 Release date: 2021-05-19

Released

DECLARATION OF CONFORMITY

7331791-ADH-A-000-0002-UE

REF	Name	Class	GMDN code
8015	Provox Adhesive Strip	I	62175

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.

Document No: 10000045924 Edition: 02 Release date: 2021-05-19

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Approved:	OP	Martin Richardson - MARRIC	2021-10-29 - 11:26
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-10-29 - 11:37

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Adhesives

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

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
There are more than one Intended Use in this declaration of conformity. The Intended Use for each group is stated before the group table.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

Released
Document No: 10000043861 Edition: 07 Release date: 2021-10-29

DECLARATION OF CONFORMITY

7331791-ADH-0-000-0000-CQ

Intended Use:
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.

REF	Name	Class	GMDN code
7253	Provox Adhesive Flexiderm Round	I	62175
7254	Provox Adhesive Flexiderm Oval	I	62175
7255	Provox Adhesive Optiderm Round	I	62175
7256	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
7332	Provox Adhesive OptiDerm Plus	I	62175
7265	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

Intended Use:
The Provox StabiliBase adhesive is a single use device intended for laryngectomized patients breathing through a tracheostoma. The device is attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.

REF	Name	Class	GMDN code
7289	Provox StabiliBase (15 pcs)	I	62175
7299	Provox StabiliBase (3 pcs)	I	62175

Intended Use:
The Provox StabiliBase OptiDerm is a single use adhesive intended for laryngectomized patients breathing through a tracheostoma. The device is attached to the skin around the tracheostoma in order to provide connection for components of the Provox HME system. The adhesive is suitable (also) for sensitive and/or breached skin and for deep tracheostomas.

REF	Name	Class	GMDN code
7318	Provox StabiliBase OptiDerm (15pc)	I	62175
7328	Provox StabiliBase OptiDerm (3pcs)	I	62175

Intended Use:
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.

REF	Name	Class	GMDN code
8014	Provox Luna Adhesive	I	62175

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

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Approved:	OP	Martin Richardson - MARRIC	2022-01-11 - 09:14
Released:	QA	Ulrika Svensson - SEHRBHNU	2022-01-11 - 09:35

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Cleaning Towel

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

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

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
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Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045925 Edition: 02 Release date: 2022-01-11

Released

DECLARATION OF CONFORMITY

7331791-ADH-A-000-0003-UH

REF	Name	Class	GMDN code
7244	Provox Cleaning Towel 10-p	I	46205

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.

Document No: 10000045925 Edition: 02 Release date: 2022-01-11

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Approved:	OP	Martin Richardson - MARRIC	2021-12-10 - 14:59
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-12-13 - 08:11

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® HME Cassette Adaptor, Provox® BasePlate Adaptor

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

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
There are more than one Intended Use in this declaration of conformity. The Intended Use for each group is stated before the group table.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

Released
Document No: 10000045944 Edition: 04 Release date: 2021-12-13

DECLARATION OF CONFORMITY

7331791-HME-A-000-0003-F5

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

REF	Name	Class	GMDN code
7246	Provox HME Cassette Adaptor	I	63623

Intended Use:
The Provox BasePlate Adaptor ("adaptor") is an accessory product for rehabilitation after total laryngectomy. It allows attaching medical devices, (HME), with ISO 15mm standard connector to a tracheostoma by fitting it into a Provox Adhesive base plate, Provox LaryButton or Provox LaryTube. A typical example would be to attach an HME with built-in oxygen adapter (TrachPhone). For single patient use.

REF	Name	Class	GMDN code
7263	Provox 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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Document No: 10000045944 Edition: 04 Release date: 2021-12-13

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Approved:	OP	Martin Richardson - MARRIC	2021-12-07 - 17:00
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-12-08 - 07:59

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® ShowerAid, Provox® Luna® ShowerAid

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

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
There are more than one Intended Use in this declaration of conformity. The Intended Use for each group is stated before the group table.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045932 Edition: 02 Release date: 2021-12-08

Released

DECLARATION OF CONFORMITY

7331791-ADH-A-000-0000-U8

Intended Use:
The Provox ShowerAid is used to temporarily replace the Provox XtraMoist/Provox XtraFlow/Provox FreeHands/Provox FreeHands FlexiVoice/Provox Micron HME during showering. The device is for single patient use.

REF	Name	Class	GMDN code
7260	Provox ShowerAid	I	62047

Intended Use:
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.

REF	Name	Class	GMDN code
8016	Provox Luna ShowerAid	I	62047

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.

Document No: 10000045932 Edition: 02 Release date: 2021-12-08

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Approved:	OP	Martin Richardson - MARRIC	2021-05-18 - 17:24
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 11:45

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

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 clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

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: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00
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Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045946 Edition: 01 Release date: 2021-05-19

Released

DECLARATION OF CONFORMITY

7331791-GEN-A-000-0003-EF

REF	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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Document No: 10000045946 Edition: 01 Release date: 2021-05-19

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Approved:	OP	Martin Richardson - MARRIC	2022-01-11 - 09:13
Released:	QA	Ulrika Svensson - SEHRBHNU	2022-01-11 - 09:35

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Skin Barrier, Provox® Wipes

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

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
There are more than one Intended Use in this declaration of conformity. The Intended Use for each group is stated before the group table.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045947 Edition: 03 Release date: 2022-01-11

Released

DECLARATION OF CONFORMITY

7331791-ADH-A-000-0004-UL

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

REF	Name	Class	GMDN code
8011	Provox Skin Barrier	I	58978

Intended Use:
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 indented to use before application of Provox Adhesives.

REF	Name	Class	GMDN code
8243	Provox Wipes	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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Document No: 10000045947 Edition: 03 Release date: 2022-01-11

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Approved:	OP	Martin Richardson - MARRIC	2021-05-18 - 17:24
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 11:46

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Tracheofix

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

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 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 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
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Competent Authority:
Medical Products Agency, Sweden

Document No: 10000043897 Edition: 02 Release date: 2021-05-19

Released

DECLARATION OF CONFORMITY

7331791-COM-0-000-0003-58

REF	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

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.

Document No: 10000043897 Edition: 02 Release date: 2021-05-19