Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

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:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
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Competent Authority:
Medical Products Agency, Sweden

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Released

DECLARATION OF CONFORMITY MDR CLASS I

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
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	2020-05-26 - 11:25
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-01 - 11:13

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® FreeHands FlexiVoice™

Basic UDI: 7331791-HME-0-000-0007-XW

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 FreeHands FlexiVoice combines pulmonary rehabilitation using a Heat and Moisture Exchanger with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion, in laryngectomized patients using a voice prosthesis.

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, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-HME-0-000-0007-XW

REF	Name	Class	GMDN code
7757	Provox FreeHands FlexiVoice Set Plus	I	36071
7760	Provox FreeHands FlexiVoice Set	I	36071
8161	Provox FreeHands FlexiVoice Light	I	36071
8162	Provox FreeHands FlexiVoice Medium	I	36071
8163	Provox FreeHands FlexiVoice Strong	I	36071
8165	Provox FreeHands FlexiVoice Arch (5 pcs)	I	36071
8166	Provox FreeHands FlexiVoice XtraStrong	I	36071

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	2020-05-26 - 11:24
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-01 - 11:13

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® FreeHands HME®

Basic UDI: 7331791-HME-0-000-0003-XJ

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 FreeHands HME Cassette/Moist/Flow is intended for single use for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and must be used in combination with a Provox FreeHands speaking valve, a Provox cap or DigiTop O2. Provox FreeHands combines pulmonary rehabilitation with its Heat and Moisture Exchanging functionality with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance.

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, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

Document No: 10000043731 Edition: 00 Release date: 2020-06-01

Released

DECLARATION OF CONFORMITY MDR CLASS I

7331791-HME-0-000-0003-XJ

REF	Name	Class	GMDN code
8220	Provox FreeHands HME Moist (30 pcs)	I	58705
8221	Provox FreeHands HME Flow (30 pcs)	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.

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Document title
Declaration of Conformity

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Approved:	OP	Martin Richardson - MARRIC	2020-09-02 - 13:45
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-09-02 - 15:17

This document has been electronically signed by the persons above.

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 FreeHands HME

REF	Name	Class	GMDN code
7710	Provox FreeHands HME	I	36071
7711	Provox FreeHands HME Cassette, 30 pcs	I	58705
7712	Provox FreeHands HME Cassette, 20 pcs	I	58705
7713	Provox FreeHands HME Speech Valve Membrane Light	I	36071
7714	Provox FreeHands HME Speech Valve Membrane Medium	I	36071
7715	Provox FreeHands HME Speech Valve Membrane Strong	I	36071
7716	Provox FreeHands HME Replacement Device, light	I	36071
7717	Provox FreeHands HME Replacement Device, medium	I	36071
7718	Provox FreeHands HME Cleaning and Storage Box	I	36071
7719	Provox FreeHands HME Adjustment Kit	I	36071
7720	Provox Silicone Glue	I	58978
7721	Provox FreeHands HME Replacement Device, strong	I	36071
7722	Provox FreeHands HME Replacement Device	I	36071
7730	Provox HME Cap	I	58705
8020	Provox FreeHands Support Starter Set	I	62155
8021	Provox FreeHands Support Flat	I	62155
8022	Provox FreeHands Support Medium	I	62155
8023	Provox FreeHands Support Deep	I	62155
8024	Provox FreeHands Support Adhesive (15 pcs)	I	62175
8222	Provox FreeHands HME Moist (20 pcs)	I	58705
8223	Provox FreeHands HME Flow (20 pcs)	I	58705
7401	Provox Life FreeHands Adhesive	I	62175

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.

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Notified Body:	*Intertek Semko AB, Sweden. Identification no. 0413* *EC-certificate no. 41310296-03*
Competent Authority:	*Medical Products Agency, Sweden*

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This document has been electronically signed by the persons above.

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 HME Accessories

REF	Name	Class	GMDN code
7244	Provox Cleaning Towel	I	46205
7246	Provox HME CassetteAdaptor	I	58705
7251	Provox Adhesive Regular Round	I	62175
7252	Provox Adhesive Regular Oval	I	62175
7330	Provox Adhesive Regular Plus	I	62175
7251ES	Provox Adhesive Regular Round	I	62175
7252ES	Provox Adhesive Regular Oval	I	62175
7260	Provox ShowerAid	I	62047
7263	Provox BasePlate Adaptor	I	58705
7405	Provox Life Standard Adhesive	I	62175
7406	Provox Life Sensitive Adhesive	I	62175
7465	Provox Life Sensitive Adhesive Oval B	I	62175
8011	Provox Skin Barrier	I	58978
8012	Provox Adhesive Remover	I	60494
8015	Provox Adhesive Strip	I	62175
8016	Provox Luna ShowerAid	I	62047
8238	Provox FlexiDerm Plus (3pcs)	I	62175
8239	Provox OptiDerm Plus (3pcs)	I	62175
8240	Provox Regular Plus (3pcs)	I	62175
8241	Provox Regular Round (3pcs)	I	62175
8242	Provox Regular Oval (3pcs)	I	62175
8243	Provox Wipes	I	58978
8309	Provox Day Adhesive	I	62175

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Declaration of Conformity

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.

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Notified Body:	*Intertek Semko AB, Sweden. Identification no. 0413* *EC-certificate no. 41310296-03*
Competent Authority:	*Medical Products Agency, Sweden*

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This document has been electronically signed by the persons above.

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 HME Cassettes

REF	Name	Class	GMDN code
7240	Provox HME Cassette Normal (20 pcs)	I	58705
7241	Provox HME Cassette HiFlow (20 pcs)	I	58705
7242	Provox HME Cassette Normal (30 pcs)	I	58705
7243	Provox HME Cassette HiFlow (30 pcs)	I	58705
7240C	Provox HME Cassette Normal (20 pcs)	I	58705
7241C	Provox HME Cassette HiFlow (20 pcs)	I	58705
7242C	Provox HME Cassette Normal (30 pcs)	I	58705
7243C	Provox HME Cassette HiFlow (30 pcs)	I	58705
7236	HME Compact, Normal	I	58705
7237	HME Compact, HiFlow	I	58705
7238	HME Compact, Starterkit	I	58705
7247	Provox Micron HME (5 pcs)	I	58705
7248	Provox Micron HME (30 pcs)	I	58705
7250	Provox HME StarterKit	I	58705
7257	Provox HME Let´s Start Sample Bag	I	58705
7240X	Provox XtraMoist HME (20 pcs)	I	58705
7241X	Provox XtraFlow HME (20 pcs)	I	58705
7297	Provox XtraMoist HME (5 pcs)	I	58705
7298	Provox XtraFlow HME (5 pcs)	I	58705
8224AU	Provox Coming Home Australia	I	58705
8224BEFR	Provox Coming Home Belgium/French	I	58705
8224BENL	Provox Coming Home Belgium/Dutch	I	58705
8224CA	Provox Coming Home Canada	I	58705
8224CHDE	Provox Coming Home Switzerland/German	I	58705
8224CHFR	Provox Coming Home Switzerland/French	I	58705
8224DE	Provox Coming Home Germany	I	58705

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Document title
Declaration of Conformity

8224DK	Provox Coming Home Denmark	I	58705
8224EM	Provox Coming Home Generic	I	58705
8224ES	Provox Coming Home Spain	I	58705
8224FI	Provox Coming Home Finland	I	58705
8224FR	Provox Coming Home France	I	58705
8224GB	Provox Coming Home GB	I	58705
8224IT	Provox Coming Home Italy	I	58705
8224JP	Provox Coming Home Japan	I	58705
8224NL	Provox Coming Home Netherlands	I	58705
8224NO	Provox Coming Home Norway	I	58705
8224PL	Provox Coming Home Poland	I	58705
8224PT	Provox Coming Home Portugal	I	58705
8224SE	Provox Coming Home Sweden	I	58705
8224US	Provox Coming Home USA	I	58705
8228JP	Provox Coming Home Daytime Japan	I	58705
8227AU	Provox Living Well Australia	I	58705
8227CA	Provox Living Well Canada	I	58705
8227CHDE	Provox Living Well Switzerland/German	I	58705
8227CHFR	Provox Living Well Switzerland/French	I	58705
8227DE	Provox Living Well Germany	I	58705
8227DK	Provox Living Well Denmark	I	58705
8227EM	Provox Living Well Generic	I	58705
8227ES	Provox Living Well Spain	I	58705
8227FI	Provox Living Well Finland	I	58705
8227FR	Provox Living Well France	I	58705
8227GB	Provox Living Well Great Britain	I	58705
8227IT	Provox Living Well Italy	I	58705
8227JP	Provox Living Well Japan	I	58705
8227NL	Provox Living Well Netherlands	I	58705
8227NO	Provox Living Well Norway	I	58705
8227PT	Provox Living Well Portugal	I	58705
8227SE	Provox Living Well Sweden	I	58705
8227US	Provox Living Well United States	I	58705

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. 41310296-03

Competent Authority: *Medical Products Agency, Sweden*

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This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® HMEs

Basic UDI: 7331791-HME-0-000-0000-X9

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:
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Tel: +46 (0)415 198 00
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Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-HME-0-000-0000-X9

Intended Use:
The Provox XtraHME Cassette is a single use, specialized device intended for patients breathing through a tracheostoma. It is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moist from exhaled air in the device. It partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

REF	Name	Class	GMDN code
7272	Provox XtraFlow HME (20 pcs)	I	58705
7273	Provox XtraMoist HME (20 pcs)	I	58705
7290	Provox XtraMoist HME (30 pcs)	I	58705
7290ES	Provox XtraMoist HME	I	58705
7291	Provox XtraFlow HME (30 pcs)	I	58705
7291ES	Provox XtraFlow HME	I	58705
8229	Provox XtraFlow & XtraMoist HME (5+5pcs)	I	58705

Intended Use:
The Provox Luna HME is a single use heat- and moisture exchanger, attachable to the Provox Luna Adhesive, for night-time use after total laryngectomy.

REF	Name	Class	GMDN code
8013	Provox Luna HME (30 pcs)	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.

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Released:	QA	Ulrika Svensson - SEHRBHNU	2020-09-02 - 15:21

This document has been electronically signed by the persons above.

We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing Annex II, with the exemption of section 4 (for class IIa and class IIb devices) and Annex VII (for class I devices) of the European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The Provox Lary Products

REF	Name	Class	GMDN code
7601	Provox LaryTube 8/27	IIb	38792
7602	Provox LaryTube 8/36	IIb	38792
7603	Provox LaryTube 8/55	IIb	38792
7605	Provox LaryTube 9/27	IIb	38792
7606	Provox LaryTube 9/36	IIb	38792
7607	Provox LaryTube 9/55	IIb	38792
7609	Provox LaryTube 10/27	IIb	38792
7610	Provox LaryTube 10/36	IIb	38792
7611	Provox LaryTube 10/55	IIb	38792
7613	Provox LaryTube 12/27	IIb	38792
7614	Provox LaryTube 12/36	IIb	38792
7615	Provox LaryTube 12/55	IIb	38792
7624	Provox LaryTube 8/36 with Ring	IIb	38792
7625	Provox LaryTube 8/55 with Ring	IIb	38792
7626	Provox LaryTube 9/36 with Ring	IIb	38792
7627	Provox LaryTube 9/55 with Ring	IIb	38792
7628	Provox LaryTube 10/36 with Ring	IIb	38792
7629	Provox LaryTube 10/55 with Ring	IIb	38792
7630	Provox LaryTube 12/36 with Ring	IIb	38792
7631	Provox LaryTube 12/55 with Ring	IIb	38792
7637	Provox LaryTube 8/36, Fenestrated	IIb	38792
7638	Provox LaryTube 8/55, Fenestrated	IIb	38792
7640	Provox LaryTube 9/36, Fenestrated	IIb	38792
7641	Provox LaryTube 9/55, Fenestrated	IIb	38792
7643	Provox LaryTube 10/36, Fenestrated	IIb	38792
7644	Provox LaryTube 10/55, Fenestrated	IIb	38792
7646	Provox LaryTube 12/36, Fenestrated	IIb	38792

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Document title
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7647	Provox LaryTube 12/55, Fenestrated	IIb	38792
7601FR	Provox LaryTube 8/27	IIb	38792
7602FR	Provox LaryTube 8/36	IIb	38792
7603FR	Provox LaryTube 8/55	IIb	38792
7605FR	Provox LaryTube 9/27	IIb	38792
7606FR	Provox LaryTube 9/36	IIb	38792
7607FR	Provox LaryTube 9/55	IIb	38792
7609FR	Provox LaryTube 10/27	IIb	38792
7610FR	Provox LaryTube 10/36	IIb	38792
7611FR	Provox LaryTube 10/55	IIb	38792
7613FR	Provox LaryTube 12/27	IIb	38792
7614FR	Provox LaryTube 12/36	IIb	38792
7615FR	Provox LaryTube 12/55	IIb	38792
7624FR	Provox LaryTube 8/36 with Ring	IIb	38792
7625FR	Provox LaryTube 8/55 with Ring	IIb	38792
7626FR	Provox LaryTube 9/36 with Ring	IIb	38792
7627FR	Provox LaryTube 9/55 with Ring	IIb	38792
7628FR	Provox LaryTube 10/36 with Ring	IIb	38792
7629FR	Provox LaryTube 10/55 with Ring	IIb	38792
7630FR	Provox LaryTube 12/36 with Ring	IIb	38792
7631FR	Provox LaryTube 12/55 with Ring	IIb	38792
7637FR	Provox LaryTube 8/36, Fenestrated	IIb	38792
7638FR	Provox LaryTube 8/55, Fenestrated	IIb	38792
7640FR	Provox LaryTube 9/36, Fenestrated	IIb	38792
7641FR	Provox LaryTube 9/55, Fenestrated	IIb	38792
7643FR	Provox LaryTube 10/36, Fenestrated	IIb	38792
7644FR	Provox LaryTube 10/55, Fenestrated	IIb	38792
7646FR	Provox LaryTube 12/36, Fenestrated	IIb	38792
7647FR	Provox LaryTube 12/55, Fenestrated	IIb	38792
7648	Provox LaryTube Sizer Kit	IIa	38792
7654	Provox FenestrationPunch	I	38792
7660	Provox TubeBrush 8 mm	I	34883
7661	Provox TubeBrush 12 mm	I	34883
7668	Provox TubeHolder	I	35752
7669	Provox LaryClip	I	35752
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

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8250	Provox Swab Small	I	58717
8251	Provox Swab Medium	I	58717
8252	Provox Swab Large	I	58717
8258	Provox Swab XtraLarge	I	58717
7409	Provox Life LaryTube 8/27	IIb	38792
7410	Provox Life LaryTube 8/36	IIb	38792
7411	Provox Life LaryTube 8/55	IIb	38792
7412	Provox Life LaryTube 9/27	IIb	38792
7413	Provox Life LaryTube 9/36	IIb	38792
7414	Provox Life LaryTube 9/55	IIb	38792
7415	Provox Life LaryTube 10/27	IIb	38792
7416	Provox Life LaryTube 10/36	IIb	38792
7417	Provox Life LaryTube 10/55	IIb	38792
7418	Provox Life LaryTube 12/27	IIb	38792
7419	Provox Life LaryTube 12/36	IIb	38792
7420	Provox Life LaryTube 12/55	IIb	38792
7421	Provox Life LaryTube 8/36 with Ring	IIb	38792
7422	Provox Life LaryTube 8/55 with Ring	IIb	38792
7423	Provox Life LaryTube 9/36 with Ring	IIb	38792
7424	Provox Life LaryTube 9/55 with Ring	IIb	38792
7425	Provox Life LaryTube 10/36 with Ring	IIb	38792
7426	Provox Life LaryTube 10/55 with Ring	IIb	38792
7427	Provox Life LaryTube 12/36 with Ring	IIb	38792
7428	Provox Life LaryTube 12/55 with Ring	IIb	38792
7429	Provox Life LaryTube 8/36, Fenestrated	IIb	38792
7430	Provox Life LaryTube 8/55, Fenestrated	IIb	38792
7431	Provox Life LaryTube 9/36, Fenestrated	IIb	38792
7432	Provox Life LaryTube 9/55, Fenestrated	IIb	38792
7433	Provox Life LaryTube 10/36, Fenestrated	IIb	38792
7434	Provox Life LaryTube 10/55, Fenestrated	IIb	38792
7435	Provox Life LaryTube 12/36, Fenestrated	IIb	38792
7436	Provox Life LaryTube 12/55, Fenestrated	IIb	38792

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. 41310296-03

Competent Authority: *Medical Products Agency, Sweden*

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Released:	QA	Ulrika Svensson - SEHRBHNU	2020-08-25 - 09:08

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® Life™ Adhesives

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

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 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:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-ADH-0-000-0001-CT

REF	Name	Class	GMDN code
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
7466	Provox Life Sensitive Adhesive Plus	I	62175
8261	Provox Life Night Adhesive	I	62175
8263	Provox Life Stability 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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This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® Life™ HMEs

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

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:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-HME-0-000-0001-XC

Intended use/purpose:
Provox Life HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma.

REF	Name	Class	GMDN code
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
8262	Provox Life Night HME	I	58705

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 or a DigiTop.

REF	Name	Class	GMDN code
7440	Provox Life FreeHands HME	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.

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Released:	QA	Karolina Nilsson - KARNIL	2020-08-21 - 15:54

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® Life™ Shower

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

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 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 above

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

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
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Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-ADH-A-000-0001-UB

REF	Name	Class	GMDN code
8308	Provox Life Shower	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.

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Approved:	OP	Martin Richardson - MARRIC	2020-06-05 - 09:40
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-06-16 - 11:09

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® Luna® Set

Basic UDI: 7331791-KIT-0-000-0002-HS

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 Luna Set is a combination of Provox Luna HME and Provox Luna Adhesive.

Provox Luna HME: The Provox Luna HME is a single use heat- and moisture exchanger, attachable to the Provox Luna Adhesive, for night-time use after total laryngectomy.

Provox Luna Adhesive: 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 above

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

Manufacturer:
Atos Medical AB, Kraftgatan 8, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY MDR CLASS I

7331791-KIT-0-000-0002-HS

REF	Name	Class	GMDN code
8025	Provox Luna Set	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.