Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-02-19 - 14:55
Reviewed:	QA	John Wennborg - JOHWEN	2021-02-19 - 14:59
Approved:	OP	Martin Richardson - MARRIC	2021-02-19 - 15:17
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-02-19 - 15:18

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Coming Home

Basic UDI: 7331791-KIT-0-000-0000-HL

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 Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home.

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
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

Document No: 10000045999 Edition: 02 Release date: 2021-02-19

Released

DECLARATION OF CONFORMITY

7331791-KIT-0-000-0000-HL

REF	Name	Class	GMDN code
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
8224DK	Provox Life Coming Home Denmark	I	58705
8224EM	Provox Coming Home Generic	I	58705
8224ES	Provox Coming Home Spain	I	58705
8224FI	Provox Life 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 Life 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

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: 10000045999 Edition: 02 Release date: 2021-02-19

Released

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2020-12-03 - 14:52
Reviewed:	QA	John Wennborg - JOHWEN	2020-12-07 - 11:46
Approved:	OP	Martin Richardson - MARRIC	2020-12-07 - 12:18
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-12-07 - 12:58

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

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:
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: 1000043873 Edition: 01 Release date: 2020-12-07

Released

DECLARATION OF CONFORMITY

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.

Document No: 1000043873 Edition: 01 Release date: 2020-12-07

Released

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2020-12-03 - 14:57
Reviewed:	QA	John Wennborg - JOHWEN	2020-12-07 - 11:47
Approved:	OP	Martin Richardson - MARRIC	2020-12-07 - 12:18
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-12-07 - 12:59

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

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, 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

Released
Document No: 10000043981 Edition: 01 Release date: 2020-12-07

DECLARATION OF CONFORMITY

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.

Released
Document No: 10000043981 Edition: 01 Release date: 2020-12-07

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-02-17 - 15:55
Reviewed:	QA	John Wennborg - JOHWEN	2021-02-17 - 16:36
Approved:	OP	Martin Richardson - MARRIC	2021-02-17 - 17:32
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-02-17 - 17:35

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Micron HME™

Basic UDI: 7331791-HME-0-000-0002-XF

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 Micron HME is a heat and moisture exchanger (HME) and air filtration device for patients breathing through a tracheostoma. Provox Micron HME partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing. Provox Micron HME is intended to be used with the attachment devices in the Provox HME System.

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
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

Released
Document No: 10000045951 Edition: 01 Release date: 2021-02-17

DECLARATION OF CONFORMITY

7331791-HME-0-000-0002-XF

REF	Name	Class	GMDN code
7247	Provox Micron HME (5 pcs)	I	58705
7248	Provox Micron 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.

Released
Document No: 10000045951 Edition: 01 Release date: 2021-02-17