Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 16:16
Reviewed:	QA	John Wennborg - JOHWEN	2021-05-20 - 09:05
Approved:	OP	Martin Richardson - MARRIC	2021-05-20 - 09:08
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-21 - 14:05

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Life™ Experience Packs

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

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

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

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

Hörby, Sweden date as stated above

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

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

Competent Authority:
Medical Products Agency, Sweden

Document No: 1000004781 0 Edition: 00 Release date: 2021-05-21

Released

DECLARATION OF CONFORMITY

7331791-KIT-0-000-0005-J3

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

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

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

Document No: 1000004781O Edition: 00 Release date: 2021-05-21

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Approved:	OP	Martin Richardson - MARRIC	2021-05-25 - 08:20
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-25 - 13:35

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

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: 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: 10000043983 Edition: 10 Release date: 2021-05-25

Released

DECLARATION OF CONFORMITY

7331791-ADH-0-000-0001-CT

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

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: 10000043983 Edition: 10 Release date: 2021-05-25

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Approved:	OP	Martin Richardson - MARRIC	2021-05-19 - 11:56
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 17:00

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Life™ BasePlate Adaptor

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

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

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

Hörby, Sweden date as stated above

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

Manufacturer: 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

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DECLARATION OF CONFORMITY

7331791-HME-A-000-0005-FB

REF	Name	Class	GMDN code
8057	Provox Life BasePlate Adaptor	I	58705

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

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

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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 17:01

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® Life™ FreeHands HME

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

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 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.

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

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Released

DECLARATION OF CONFORMITY

7331791-HME-0-000-0008-XZ

REF	Name	Class	GMDN code
7440	Provox Life FreeHands HME	I	58705
7477	Provox Life Sample Pack 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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Approved:	OP	Martin Richardson - MARRIC	2021-05-21 - 15:26
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-21 - 15:28

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

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:
Provox Life HMEs are single use heat- and moisture exchangers for patients breathing through a 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

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Released

DECLARATION OF CONFORMITY

7331791-HME-0-000-0001-XC

REF	Name	Class	GMDN code
7475	Provox Life Sample Pack Protect HME	I	58705
7476	Provox Life Sample Pack Energy HME	I	58705
8072	Provox Life Night HME Experience	I	58705
8073	Provox Life Energy HME Experience	I	58705
8074	Provox Life Protect HME Experience	I	58705
8262	Provox Life Night HME	I	58705
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

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: 10000043985 Edition: 11 Release date: 2021-05-21

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Approved:	OP	Martin Richardson - MARRIC	2021-05-21 - 15:27
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-21 - 15:28

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Life™ Sample Packs

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

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

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

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

Hörby, Sweden date as stated above

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

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

Competent Authority:
Medical Products Agency, Sweden

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Released

DECLARATION OF CONFORMITY

7331791-KIT-0-000-0003-HV

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

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

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

Document No: 10000046701 Edition: 02 Release date: 2021-05-21

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Approved:	OP	Martin Richardson - MARRIC	2021-05-19 - 11:55
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 17:01

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

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: 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

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DECLARATION OF CONFORMITY

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.