Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 11:40

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

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: 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: 10000043825 Edition: 03 Release date: 2021-05-19

Released

DECLARATION OF CONFORMITY

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
8210	Provox Life FreeHands FlexiVoice Set Plus	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.

Document No: 10000043825 Edition: 03 Release date: 2021-05-19

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Approved:	OP	Martin Richardson - MARRIC	2021-05-27 - 10:39

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

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: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
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Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

DECLARATION OF CONFORMITY

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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DECLARATION OF CONFORMITY

Provox® FreeHands Support™

Basic UDI: 7331791-HME-A-000-0000-EU

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 Support provides support to the Provox Adhesive when using a Provox hands-free speaking valve after total laryngectomy. The device is a single patient use device with a single use adhesive.

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
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Competent Authority:
Medical Products Agency, Sweden

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Document No: 10000045929 Edition: 02 Release date: 2021-12-13

DECLARATION OF CONFORMITY

7331791-HME-A-000-0000-EU

REF	Name	Class	GMDN code
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

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: 10000045929 Edition: 02 Release date: 2021-12-13

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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 11:41

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Atos

DECLARATION OF CONFORMITY

Provox® FreeHands Support™ Adhesive

Basic UDI: 7331791-HME-A-000-0004-F8

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 Support provides support to the Provox Adhesive when using a Provox hands-free speaking valve after total laryngectomy. The device is a single patient use device with a single use adhesive.

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-A-000-0004-F8

REF	Name	Class	GMDN code
8024	Provox FreeHands Support Adhesive (15pc)	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: 10000045930 Edition: 01 Release date: 2021-05-19

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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 11:40

This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY

Provox® HME Cap™

Basic UDI: 7331791-HME-A-000-0002-F2

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 HME Cap is a single patient use, dome-shaped titanium ring, that allows use of Provox FreeHands HME cassette (REF 8220, 8221) without Provox FreeHands FlexiVoice.

Provox HME Cap is only intended for use when using Provox FreeHands FlexiVoice is not recommended, i.e. when sleeping.

Provox HME Cap cannot be used with any other type of HME cassette. The front opening of the cap can be occluded manually to speak. Provox HME Cap can be cleaned and reused.

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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DECLARATION OF CONFORMITY

7331791-HME-A-000-0002-F2

REF	Name	Class	GMDN code
7730	Provox HME Cap	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.