

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-21 - 07:43
Reviewed:	QA	John Wennborg - JOHWEN	2021-05-21 - 08:51
Approved:	OP	Martin Richardson - MARRIC	2021-05-21 - 09:31
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-25 - 13:37

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 Accessories

REF	Name	Class	GMDN code
7122	Provox Dilator 17	IIa	62125
7123	Provox Dilator 20	IIa	62125
7211	Provox Dilator	IIa	62125
7205	Provox Plug	IIa	62119
8119	Provox Vega Plug 17	IIa	62119
8119-18	Provox Vega Plug 17	IIa	62119
8129	Provox Vega Plug 20	IIa	62119
8129-18	Provox Vega Plug 20	IIa	62119
8139	Provox Vega Plug 22.5	IIa	62119
8139-18	Provox Vega Plug 22.5	IIa	62119
7215	Provox Guide Wire	IIa	65394
7275	Provox XtraFlange 22.5	IIb	42533
7276	Provox XtraFlange 20	IIb	42533
7277	Provox XtraFlange 17	IIb	42533

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. 41310296-04*

Competent Authority: *Medical Products Agency, Sweden*

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Issued:	DD	Mårten Cervin - SEHRBCNM	2021-07-07 - 17:00
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Released:	QA	Ulrika Svensson - SEHRBHNU	2021-07-08 - 12:01

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Brush

Basic UDI: 7331791-VPS-A-000-0003-RR

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 Brush is used for cleaning of all Provox voice prostheses.
The Provox Brush is used for cleaning of LaryTube fenestrations.
The Provox Brush is used for application of Fluorosilicone oil in ActiValve.
The Provox Brush may be used for application of Anti-Candida medications into a voice prosthesis.
The distal end of the Provox Brush is used as insertion tool for the Provox Plug.
The Provox Brush is intended for use by the patient.
The Brush is intended for single patient re-use.

Hörby, Sweden date as stated above



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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

DECLARATION OF CONFORMITY

7331791-VPS-A-000-0003-RR

REF	Name	Class	GMDN code
7204	Provox Brush	I	62095
7204-18	Provox Brush	I	62095
7225	Provox Brush XL	I	62095
7225-18	Provox Brush XL	I	62095
8404	Provox Brush Long	I	62095
8425	Provox Brush Long XL	I	62095

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 - 11:38

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Atos

DECLARATION OF CONFORMITY

Provox[®] Capsule

Basic UDI: 7331791-VPS-A-000-0000-RG

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 Capsule is a single use accessory for anterograde insertion of a standard voice prosthesis by a clinician into the tracheoesophageal puncture of laryngectomized patients.

Hörby, Sweden date as stated above



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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

DECLARATION OF CONFORMITY

7331791-VPS-A-000-0000-RG

REF	Name	Class	GMDN code
7795	Provox Capsule 17Fr	I	62134
7796	Provox Capsule 20Fr	I	62134
7797	Provox Capsule 22.5Fr	I	62134

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	2021-05-25 - 13:33

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Flush

Basic UDI: 7331791-VPS-A-000-0001-RK

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 Flush is intended to be used to flush drinking water or air through the inner lumen of a Provox voice prosthesis for cleaning purposes. The Flush is intended for both home and clinical use by patient or clinician.

Hörby, Sweden date as stated above



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

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Competent Authority:

Medical Products Agency, Sweden

DECLARATION OF CONFORMITY

7331791-VPS-A-000-0001-RK

REF	Name	Class	GMDN code
8109	Provox Flush	I	62096
8109-18	Provox Flush	I	62096

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.

Atos

DECLARATION OF CONFORMITY

Provox[®] Measure, Provox[®] Measure Flanges

Basic UDI: 7331791-VPS-A-00R-0005-BK

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 Measure is intended for sizing the length (corresponding to voice prosthesis length) of tracheoesophageal (TE) punctures.

Hörby, Sweden date as stated above

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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

DECLARATION OF CONFORMITY

7331791-VPS-A-00R-0005-BK

REF	Name	Class	GMDN code
7270	Provox Measure	I	62126
7271	Provox Measure Flanges	I	62126

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 - 11:38

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Protector

Basic UDI: 7331791-TEX-0-000-0001-WN

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 Protector is a reusable cover that provides protection and 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

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Competent Authority:

Medical Products Agency, Sweden

DECLARATION OF CONFORMITY

7331791-TEX-0-000-0001-WN

REF	Name	Class	GMDN code
7385	Provox Protector Small White	I	31065
7386	Provox Protector Large White	I	31065
7387	Provox Protector Slim Small White	I	31065
7388	Provox Protector Slim Small Blue	I	31065
7389	Provox Protector Slim Large White	I	31065
7390	Provox Protector Slim Large Blue	I	31065
7391	Provox Protector Air Small White	I	31065
7392	Provox Protector Air Small Blue	I	31065
7393	Provox Protector Air Large White	I	31065
7394	Provox Protector Air Large Blue	I	31065

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.

Atos

DECLARATION OF CONFORMITY

Provox® TwistLock

Basic UDI: 7331791-VPS-A-000-0009-SB

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 TwistLock is a single use Provox Insertion System accessory for easier loading of Provox Vega Voice Prosthesis into Provox Capsule by clinician.

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

DECLARATION OF CONFORMITY

7331791-VPS-A-000-0009-SB

REF	Name	Class	GMDN code
8030	Provox TwistLock 17Fr	I	63307
8031	Provox TwistLock 20Fr	I	63307
8032	Provox TwistLock 22.5Fr	I	63307

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.