

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 ActiValve System

REF	Name	Class	GMDN code
7150	Provox ActiValve Light 4.5 mm	IIb	42533
7151	Provox ActiValve Light 6 mm	IIb	42533
7152	Provox ActiValve Light 8 mm	IIb	42533
7153	Provox ActiValve Light 10 mm	IIb	42533
7154	Provox ActiValve Light 12.5 mm	IIb	42533
7160	Provox ActiValve Strong 4.5 mm	IIb	42533
7161	Provox ActiValve Strong 6 mm	IIb	42533
7162	Provox ActiValve Strong 8 mm	IIb	42533
7163	Provox ActiValve Strong 10 mm	IIb	42533
7164	Provox ActiValve Strong 12.5 mm	IIb	42533
7165	Provox ActiValve XtraStrong 4.5 mm	IIb	42533
7166	Provox ActiValve XtraStrong 6 mm	IIb	42533
7167	Provox ActiValve XtraStrong 8 mm	IIb	42533
7168	Provox ActiValve XtraStrong 10 mm	IIb	42533
7169	Provox ActiValve XtraStrong 12.5 mm	IIb	42533
7149	ActiValve Lubricant	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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Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 07-Sep-2023 12:41:57 GMT+0000
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Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Karolina Nilsson - KARNIL	2023-07-13 - 16:29
Reviewed:	QA	John Wennborg - JOHWEN	2023-07-13 - 16:53
Approved:	OP	Martin Richardson - MARRIC	2023-07-13 - 17:02
Released:			

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY FOR THE PRODUCT(S)

Provox® Electrolarynx

Basic UDI: 7331791-ELX-0-A00-0001-VJ

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, any other applicable Union legislation and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and, UK Medical Devices Regulations 2002, including amendments in effect at the issuance date.

Intended use/purpose:

An electrolarynx is a battery-powered artificial larynx that is externally applied and intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, or by insertion of a tube in the oral cavity (with an oral adapter), the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

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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SRN number: SE-MF-00000725

Competent Authority Medical Products Agency
Sweden

Document No: 10000048270 Edition: 07 Release date: 2023-07-13

Released

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-ELX-0-A00-0001-VJ

REF	Device name	Class	GMDN code
7438	Provox SolaTone Plus	I	34857
7439	Provox TruTone Emote	I	34857
7444	Provox TruTone Plus	I	34857

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.

In compliance with UK Medical Devices Regulations 2002 as amended


Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:

Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)

- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

 atosmedical.com	Document title
	Declaration of Conformity

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2020-11-16 - 13:35
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Approved:	OP	Martin Richardson - MARRIC	2020-11-16 - 21:36
Released:	QA	Ulrika Svensson - SEHRBHNU	2020-11-17 - 08:26

This document has been electronically signed by the persons above.

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The Provox NID Voice Prosthesis System

REF	Name	Class	GMDN code
7101	Provox NID 17, 6mm	IIb	44412
7102	Provox NID 17, 8mm	IIb	44412
7103	Provox NID 17, 10mm	IIb	44412
7104	Provox NID 17, 12mm	IIb	44412
7105	Provox NID 17, 14mm	IIb	44412
7106	Provox NID 17, 18mm	IIb	44412
7111	Provox NID 20, 6mm	IIb	44412
7112	Provox NID 20, 8mm	IIb	44412
7113	Provox NID 20, 10mm	IIb	44412
7114	Provox NID 20, 12mm	IIb	44412
7115	Provox NID 20, 14mm	IIb	44412
7116	Provox NID 20, 18mm	IIb	44412

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
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Competent Authority: Medical Products Agency, Sweden

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The Provox Vega System

REF	Name	Class	GMDN code
8140	Provox Vega Puncture Set 17Fr 8mm	IIb	42533
8141	Provox Vega Puncture Set 17Fr 10mm	IIb	42533
8142	Provox Vega Puncture Set 17Fr 12,5mm	IIb	42533
8143	Provox Vega Puncture Set 17Fr 15mm	IIb	42533
8144	Provox Vega Puncture Set 20Fr 8mm	IIb	42533
8145	Provox Vega Puncture Set 20Fr 10mm	IIb	42533
8146	Provox Vega Puncture Set 20Fr 12,5mm	IIb	42533
8147	Provox Vega Puncture Set 22,5Fr 8mm	IIb	42533
8148	Provox Vega Puncture Set 22,5Fr 10mm	IIb	42533
8149	Provox Vega Puncture Set 22,5Fr 12,5mm	IIb	42533
8140US	Provox Vega Puncture Set 17Fr 8mm	IIb	42533
8141US	Provox Vega Puncture Set 17Fr 10mm	IIb	42533
8142US	Provox Vega Puncture Set 17Fr 12,5mm	IIb	42533
8143US	Provox Vega Puncture Set 17Fr 15mm	IIb	42533
8144US	Provox Vega Puncture Set 20Fr 8mm	IIb	42533
8145US	Provox Vega Puncture Set 20Fr 10mm	IIb	42533
8146US	Provox Vega Puncture Set 20Fr 12,5mm	IIb	42533
8147US	Provox Vega Puncture Set 22,5Fr 8mm	IIb	42533
8148US	Provox Vega Puncture Set 22,5Fr 10mm	IIb	42533
8149US	Provox Vega Puncture Set 22,5Fr 12,5mm	IIb	42533
8140-18	Provox Vega Puncture Set 17Fr 8mm	IIb	42533
8141-18	Provox Vega Puncture Set 17Fr 10mm	IIb	42533
8142-18	Provox Vega Puncture Set 17Fr 12,5mm	IIb	42533
8143-18	Provox Vega Puncture Set 17Fr 15mm	IIb	42533
8144-18	Provox Vega Puncture Set 20Fr 8mm	IIb	42533
8145-18	Provox Vega Puncture Set 20Fr 10mm	IIb	42533
8146-18	Provox Vega Puncture Set 20Fr 12,5mm	IIb	42533
8147-18	Provox Vega Puncture Set 22,5Fr 8mm	IIb	42533
8148-18	Provox Vega Puncture Set 22,5Fr 10mm	IIb	42533
8149-18	Provox Vega Puncture Set 22,5Fr 12,5mm	IIb	42533
4270	Provox Vega 17Fr 4mm	IIb	42533
4271	Provox Vega 17Fr 6mm	IIb	42533
4272	Provox Vega 17Fr 8mm	IIb	42533
4273	Provox Vega 17Fr 10mm	IIb	42533
4274	Provox Vega 17Fr 12,5mm	IIb	42533
4275	Provox Vega 17Fr 15mm	IIb	42533

4276	Provox Vega 20Fr 4mm	IIb	42533
4277	Provox Vega 20Fr 6mm	IIb	42533
4278	Provox Vega 20Fr 8mm	IIb	42533
4279	Provox Vega 20Fr 10mm	IIb	42533
4280	Provox Vega 20Fr 12,5mm	IIb	42533
4281	Provox Vega 20Fr 15mm	IIb	42533
4282	Provox Vega 22,5Fr 4mm	IIb	42533
4283	Provox Vega 22,5Fr 6mm	IIb	42533
4284	Provox Vega 22,5Fr 8mm	IIb	42533
4285	Provox Vega 22,5Fr 10mm	IIb	42533
4286	Provox Vega 22,5Fr 12,5mm	IIb	42533
4287	Provox Vega 22,5Fr 15mm	IIb	42533
8270	Provox Vega 17Fr 4mm	IIb	42533
8271	Provox Vega 17Fr 6mm	IIb	42533
8272	Provox Vega 17Fr 8mm	IIb	42533
8273	Provox Vega 17Fr 10mm	IIb	42533
8274	Provox Vega 17Fr 12,5mm	IIb	42533
8275	Provox Vega 17Fr 15mm	IIb	42533
8276	Provox Vega 20Fr 4mm	IIb	42533
8277	Provox Vega 20Fr 6mm	IIb	42533
8278	Provox Vega 20Fr 8mm	IIb	42533
8279	Provox Vega 20Fr 10mm	IIb	42533
8280	Provox Vega 20Fr 12,5mm	IIb	42533
8281	Provox Vega 20Fr 15mm	IIb	42533
8282	Provox Vega 22,5Fr 4mm	IIb	42533
8283	Provox Vega 22,5Fr 6mm	IIb	42533
8284	Provox Vega 22,5Fr 8mm	IIb	42533
8285	Provox Vega 22,5Fr 10mm	IIb	42533
8286	Provox Vega 22,5Fr 12,5mm	IIb	42533
8287	Provox Vega 22,5Fr 15mm	IIb	42533
8270-18	Provox Vega 17Fr 4mm	IIb	42533
8271-18	Provox Vega 17Fr 6mm	IIb	42533
8272-18	Provox Vega 17Fr 8mm	IIb	42533
8273-18	Provox Vega 17Fr 10mm	IIb	42533
8274-18	Provox Vega 17Fr 12,5mm	IIb	42533
8275-18	Provox Vega 17Fr 15mm	IIb	42533
8276-18	Provox Vega 20Fr 4mm	IIb	42533
8277-18	Provox Vega 20Fr 6mm	IIb	42533
8278-18	Provox Vega 20Fr 8mm	IIb	42533
8279-18	Provox Vega 20Fr 10mm	IIb	42533
8280-18	Provox Vega 20Fr 12,5mm	IIb	42533
8281-18	Provox Vega 20Fr 15mm	IIb	42533
8282-18	Provox Vega 22,5Fr 4mm	IIb	42533
8283-18	Provox Vega 22,5Fr 6mm	IIb	42533

8284-18	Provox Vega 22,5Fr 8mm	IIb	42533
8285-18	Provox Vega 22,5Fr 10mm	IIb	42533
8286-18	Provox Vega 22,5Fr 12,5mm	IIb	42533
8287-18	Provox Vega 22,5Fr 15mm	IIb	42533
4288	Provox Vega XtraSeal 17Fr 4mm	IIb	42533
4289	Provox Vega XtraSeal 17Fr 6mm	IIb	42533
4290	Provox Vega XtraSeal 17Fr 8mm	IIb	42533
4291	Provox Vega XtraSeal 17Fr 10mm	IIb	42533
4292	Provox Vega XtraSeal 17Fr 12.5mm	IIb	42533
4293	Provox Vega XtraSeal 17Fr 15mm	IIb	42533
4294	Provox Vega XtraSeal 20Fr 4mm	IIb	42533
4295	Provox Vega XtraSeal 20Fr 6mm	IIb	42533
4296	Provox Vega XtraSeal 20Fr 8mm	IIb	42533
4297	Provox Vega XtraSeal 20Fr 10mm	IIb	42533
4298	Provox Vega XtraSeal 20Fr 12.5mm	IIb	42533
4299	Provox Vega XtraSeal 20Fr 15mm	IIb	42533
4300	Provox Vega XtraSeal 22.5Fr 4mm	IIb	42533
4301	Provox Vega XtraSeal 22.5Fr 6mm	IIb	42533
4302	Provox Vega XtraSeal 22.5Fr 8mm	IIb	42533
4303	Provox Vega XtraSeal 22.5Fr 10mm	IIb	42533
4304	Provox Vega XtraSeal 22.5Fr 12.5mm	IIb	42533
4305	Provox Vega XtraSeal 22.5Fr 15mm	IIb	42533
8288	Provox Vega XtraSeal 17Fr 4mm	IIb	42533
8289	Provox Vega XtraSeal 17Fr 6mm	IIb	42533
8290	Provox Vega XtraSeal 17Fr 8mm	IIb	42533
8291	Provox Vega XtraSeal 17Fr 10mm	IIb	42533
8292	Provox Vega XtraSeal 17Fr 12.5mm	IIb	42533
8293	Provox Vega XtraSeal 17Fr 15mm	IIb	42533
8294	Provox Vega XtraSeal 20Fr 4mm	IIb	42533
8295	Provox Vega XtraSeal 20Fr 6mm	IIb	42533
8296	Provox Vega XtraSeal 20Fr 8mm	IIb	42533
8297	Provox Vega XtraSeal 20Fr 10mm	IIb	42533
8298	Provox Vega XtraSeal 20Fr 12.5mm	IIb	42533
8299	Provox Vega XtraSeal 20Fr 15mm	IIb	42533
8300	Provox Vega XtraSeal 22.5Fr 4mm	IIb	42533
8301	Provox Vega XtraSeal 22.5Fr 6mm	IIb	42533
8302	Provox Vega XtraSeal 22.5Fr 8mm	IIb	42533
8303	Provox Vega XtraSeal 22.5Fr 10mm	IIb	42533
8304	Provox Vega XtraSeal 22.5Fr 12.5mm	IIb	42533
8305	Provox Vega XtraSeal 22.5Fr 15mm	IIb	42533
8288-18	Provox Vega XtraSeal 17Fr 4mm	IIb	42533
8289-18	Provox Vega XtraSeal 17Fr 6mm	IIb	42533
8290-18	Provox Vega XtraSeal 17Fr 8mm	IIb	42533
8291-18	Provox Vega XtraSeal 17Fr 10mm	IIb	42533

8292-18	Provox Vega XtraSeal 17Fr 12.5mm	IIb	42533
8293-18	Provox Vega XtraSeal 17Fr 15mm	IIb	42533
8294-18	Provox Vega XtraSeal 20Fr 4mm	IIb	42533
8295-18	Provox Vega XtraSeal 20Fr 6mm	IIb	42533
8296-18	Provox Vega XtraSeal 20Fr 8mm	IIb	42533
8297-18	Provox Vega XtraSeal 20Fr 10mm	IIb	42533
8298-18	Provox Vega XtraSeal 20Fr 12.5mm	IIb	42533
8299-18	Provox Vega XtraSeal 20Fr 15mm	IIb	42533
8300-18	Provox Vega XtraSeal 22.5Fr 4mm	IIb	42533
8301-18	Provox Vega XtraSeal 22.5Fr 6mm	IIb	42533
8302-18	Provox Vega XtraSeal 22.5Fr 8mm	IIb	42533
8303-18	Provox Vega XtraSeal 22.5Fr 10mm	IIb	42533
8304-18	Provox Vega XtraSeal 22.5Fr 12.5mm	IIb	42533
8305-18	Provox Vega XtraSeal 22.5Fr 15mm	IIb	42533

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Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 27-May-2024 07:01:52 GMT+0000
Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 28-May-2024 19:28:09 GMT+0000

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 Provox2 Voice Prosthesis System

REF	Name	Class	GMDN code
7216	Provox2 4,5 mm	IIb	42533
7217	Provox2 6 mm	IIb	42533
7218	Provox2 8 mm	IIb	42533
7219	Provox2 10 mm	IIb	42533
7221	Provox2 12,5 mm	IIb	42533
7224	Provox2 15 mm	IIb	42533

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Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 25-Jan-2024 18:44:29 GMT+0000
Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 26-Jan-2024 10:31:39 GMT+0000