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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	62094
7151	Provox ActiValve Light 6 mm	IIb	62094
7152	Provox ActiValve Light 8 mm	IIb	62094
7153	Provox ActiValve Light 10 mm	IIb	62094
7154	Provox ActiValve Light 12.5 mm	IIb	62094
7160	Provox ActiValve Strong 4.5 mm	IIb	62094
7161	Provox ActiValve Strong 6 mm	IIb	62094
7162	Provox ActiValve Strong 8 mm	IIb	62094
7163	Provox ActiValve Strong 10 mm	IIb	62094
7164	Provox ActiValve Strong 12.5 mm	IIb	62094
7165	Provox ActiValve XtraStrong 4.5 mm	IIb	62094
7166	Provox ActiValve XtraStrong 6 mm	IIb	62094
7167	Provox ActiValve XtraStrong 8 mm	IIb	62094
7168	Provox ActiValve XtraStrong 10 mm	IIb	62094
7169	Provox ActiValve XtraStrong 12.5 mm	IIb	62094
7149	ActiValve Lubricant	IIb	62094

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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. 41310296-03

Competent Authority: Medical Products Agency, Sweden

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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

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The Provox Vega System

REF	Name	Class	GMDN code
7770	Provox Vega XtraSeal 17Fr, 4mm	IIb	42533
7771	Provox Vega XtraSeal 17Fr, 6mm	IIb	42533
7772	Provox Vega XtraSeal 17Fr, 8mm	IIb	42533
7773	Provox Vega XtraSeal 17Fr, 10mm	IIb	42533
7774	Provox Vega XtraSeal 17Fr, 12.5mm	IIb	42533
7775	Provox Vega XtraSeal 17Fr, 15mm	IIb	42533
7776	Provox Vega XtraSeal 20Fr, 4mm	IIb	42533
7777	Provox Vega XtraSeal 20Fr, 6mm	IIb	42533
7778	Provox Vega XtraSeal 20Fr, 8mm	IIb	42533
7779	Provox Vega XtraSeal 20Fr, 10mm	IIb	42533
7780	Provox Vega XtraSeal 20Fr, 12.5mm	IIb	42533
7781	Provox Vega XtraSeal 20Fr, 15mm	IIb	42533
7782	Provox Vega XtraSeal 22.5Fr, 4mm	IIb	42533
7783	Provox Vega XtraSeal 22.5Fr, 6mm	IIb	42533
7784	Provox Vega XtraSeal 22.5Fr, 8mm	IIb	42533
7785	Provox Vega XtraSeal 22.5Fr, 10mm	IIb	42533
7786	Provox Vega XtraSeal 22.5Fr, 12.5mm	IIb	42533
7787	Provox Vega XtraSeal 22.5Fr, 15mm	IIb	42533
8110	Provox Vega 17Fr, 4 mm	IIb	42533
8111	Provox Vega 17Fr, 6 mm	IIb	42533
8112	Provox Vega 17Fr, 8 mm	IIb	42533
8113	Provox Vega 17Fr, 10 mm	IIb	42533
8114	Provox Vega 17Fr, 12.5 mm	IIb	42533
8115	Provox Vega 17Fr, 15 mm	IIb	42533
8120	Provox Vega 20Fr, 4 mm	IIb	42533
8121	Provox Vega 20Fr, 6 mm	IIb	42533

8122	Provox Vega 20Fr, 8 mm	IIb	42533
8123	Provox Vega 20Fr, 10 mm	IIb	42533
8124	Provox Vega 20Fr, 12.5 mm	IIb	42533
8125	Provox Vega 20Fr, 15 mm	IIb	42533
8130	Provox Vega 22.5Fr, 4 mm	IIb	42533
8131	Provox Vega 22.5Fr, 6 mm	IIb	42533
8132	Provox Vega 22.5Fr, 8 mm	IIb	42533
8133	Provox Vega 22.5Fr, 10 mm	IIb	42533
8134	Provox Vega 22.5Fr, 12.5 mm	IIb	42533
8135	Provox Vega 22.5Fr, 15 mm	IIb	42533
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
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
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


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 EC-certificate no. 41310296-03

Competent Authority: Medical Products Agency, Sweden

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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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The Provox Accessories

REF	Name	Class	GMDN code
7122	Provox Dilator 17	IIa	62125
7123	Provox Dilator 20	IIa	62125
7211	Provox Dilator	IIa	11263
7204	Provox Brush	I	62095
7225	Provox Brush XL	I	62095
8109	Provox Flush	I	62096
7205	Provox Plug	IIa	62119
8119	Provox Vega Plug 17	IIa	62119
8129	Provox Vega Plug 20	IIa	62119
8139	Provox Vega Plug 22.5	IIa	62119
7215	Provox Guide Wire	IIa	45623
7210	Provox Pharynx Protector	I	45919
7203	Provox Trocar	I	45919
7270	Provox Measure	I	42533
7271	Provox Measure Flanges	I	42533
7275	Provox XtraFlange 22.5	IIb	42533
7276	Provox XtraFlange 20	IIb	42533
7277	Provox XtraFlange 17	IIb	42533
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
7794	Provox Capsule 16Fr	I	62134
7795	Provox Capsule 17Fr	I	62134
7796	Provox Capsule 20Fr	I	62134
7797	Provox Capsule 22.5Fr	I	62134
8017	Provox Insertion System 17Fr	I	62127
8018	Provox Insertion System 20Fr	I	62127
8019	Provox Insertion System 22.5Fr	I	62127
8030	Provox TwistLock 17Fr	I	63307
8031	Provox TwistLock 20Fr	I	63307
8032	Provox TwistLock 22,5Fr	I	63307

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