

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 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

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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