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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Document Approvals

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