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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Approved Date: 2026-01-16

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