

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

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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