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 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

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: 2026-02-03

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