We, Atos Medical AB, hereby declare that the below mentioned Procedure Packs 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 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and, UK Medical Devices Regulations 2002, including amendments in effect at the issuance date.

The included class I devices comply with European Medical Devices Regulation (EU) 2017/745 Article 22, Systems and procedure packs.

The Provox Life LP Kit

REF	Name	Class	GMDN code
6130	Provox Life LP Kit 1 - LT 8/36, 8/55	IIb*	12292**
6131	Provox Life LP Kit 2 - LT 9/36, 9/55	IIb*	12292**
6132	Provox Life LP Kit 3 - LT 10/36,10/55	IIb*	12292**
6133	Provox Life LP Kit 4 - LT 12/36,12/55	IIb*	12292**
6134	Provox Life LP Kit 5 - LT 8/36, 8/55	IIb*	12292**
6135	Provox Life LP Kit 6 - LT 9/36, 9/55	IIb*	12292**
6136	Provox Life LP Kit 7 - LT 10/36,10/55	IIb*	12292**
6137	Provox Life LP Kit 8 - LT 12/36,12/55	IIb*	12292**
6138	Provox Life LP Kit 9 - LT 8/36, 8/55	IIb*	12292**
6139	Provox Life LP Kit 10 - LT 9/36, 9/55	IIb*	12292**
6140	Provox Life LP Kit 11- LT 10/36,10/55	IIb*	12292**
6141	Provox Life LP Kit 12 - LT 12/36,12/55	IIb*	12292**
6142	Provox Life LP Kit 13 - LT 9/55	IIb*	12292**
6143	Provox Life LP Kit 14 - LT 10/55	IIb*	12292**
6144	Provox Life LP Kit 15 - LT 10/55-2H	IIb*	12292**
6145	Provox Life LP Kit 16 - LT 10/55-2HSTP	IIb*	12292**
6146	Provox Life LP Kit 17 - LT 10/55-2HTTP	IIb*	12292**

* Highest risk class within the kit.
** GMDN code for the highest risk class device within the kit.

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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