

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 Lary Products

REF	Name	Class	GMDN code
7601	Provox LaryTube 8/27	IIb	12292
7602	Provox LaryTube 8/36	IIb	12292
7603	Provox LaryTube 8/55	IIb	12292
7605	Provox LaryTube 9/27	IIb	12292
7606	Provox LaryTube 9/36	IIb	12292
7607	Provox LaryTube 9/55	IIb	12292
7609	Provox LaryTube 10/27	IIb	12292
7610	Provox LaryTube 10/36	IIb	12292
7611	Provox LaryTube 10/55	IIb	12292
7613	Provox LaryTube 12/27	IIb	12292
7614	Provox LaryTube 12/36	IIb	12292
7615	Provox LaryTube 12/55	IIb	12292
7624	Provox LaryTube 8/36 with Ring	IIb	12292
7625	Provox LaryTube 8/55 with Ring	IIb	12292
7626	Provox LaryTube 9/36 with Ring	IIb	12292
7627	Provox LaryTube 9/55 with Ring	IIb	12292
7628	Provox LaryTube 10/36 with Ring	IIb	12292
7629	Provox LaryTube 10/55 with Ring	IIb	12292
7630	Provox LaryTube 12/36 with Ring	IIb	12292
7631	Provox LaryTube 12/55 with Ring	IIb	12292
7637	Provox LaryTube 8/36, Fenestrated	IIb	12292
7638	Provox LaryTube 8/55, Fenestrated	IIb	12292
7640	Provox LaryTube 9/36, Fenestrated	IIb	12292
7641	Provox LaryTube 9/55, Fenestrated	IIb	12292
7643	Provox LaryTube 10/36, Fenestrated	IIb	12292
7644	Provox LaryTube 10/55, Fenestrated	IIb	12292
7646	Provox LaryTube 12/36, Fenestrated	IIb	12292
7647	Provox LaryTube 12/55, Fenestrated	IIb	12292
7601FR	Provox LaryTube 8/27	IIb	12292
7602FR	Provox LaryTube 8/36	IIb	12292
7603FR	Provox LaryTube 8/55	IIb	12292
7605FR	Provox LaryTube 9/27	IIb	12292
7606FR	Provox LaryTube 9/36	IIb	12292
7607FR	Provox LaryTube 9/55	IIb	12292
7609FR	Provox LaryTube 10/27	IIb	12292
7610FR	Provox LaryTube 10/36	IIb	12292

7611FR	Provox LaryTube 10/55	IIb	12292
7613FR	Provox LaryTube 12/27	IIb	12292
7614FR	Provox LaryTube 12/36	IIb	12292
7615FR	Provox LaryTube 12/55	IIb	12292
7624FR	Provox LaryTube 8/36 with Ring	IIb	12292
7625FR	Provox LaryTube 8/55 with Ring	IIb	12292
7626FR	Provox LaryTube 9/36 with Ring	IIb	12292
7627FR	Provox LaryTube 9/55 with Ring	IIb	12292
7628FR	Provox LaryTube 10/36 with Ring	IIb	12292
7629FR	Provox LaryTube 10/55 with Ring	IIb	12292
7630FR	Provox LaryTube 12/36 with Ring	IIb	12292
7631FR	Provox LaryTube 12/55 with Ring	IIb	12292
7637FR	Provox LaryTube 8/36, Fenestrated	IIb	12292
7638FR	Provox LaryTube 8/55, Fenestrated	IIb	12292
7640FR	Provox LaryTube 9/36, Fenestrated	IIb	12292
7641FR	Provox LaryTube 9/55, Fenestrated	IIb	12292
7643FR	Provox LaryTube 10/36, Fenestrated	IIb	12292
7644FR	Provox LaryTube 10/55, Fenestrated	IIb	12292
7646FR	Provox LaryTube 12/36, Fenestrated	IIb	12292
7647FR	Provox LaryTube 12/55, Fenestrated	IIb	12292
7648	Provox LaryTube Sizer Kit	IIa	12292
7671	Provox LaryButton 12/8	IIb	14093
7672	Provox LaryButton 14/8	IIb	14093
7673	Provox LaryButton 16/8	IIb	14093
7674	Provox LaryButton 18/8	IIb	14093
7685	Provox LaryButton 12/18	IIb	14093
7686	Provox LaryButton 14/18	IIb	14093
7687	Provox LaryButton 16/18	IIb	14093
7688	Provox LaryButton 18/18	IIb	14093
7690	Provox LaryButton Sizer Kit	IIa	14093

The Provox Life Lary Products

REF	Name	Class	GMDN code
7409	Provox Life LaryTube 8/27 Standard	IIb	12292
7410	Provox Life LaryTube 8/36 Standard	IIb	12292
7411	Provox Life LaryTube 8/55 Standard	IIb	12292
7412	Provox Life LaryTube 9/27 Standard	IIb	12292
7413	Provox Life LaryTube 9/36 Standard	IIb	12292
7414	Provox Life LaryTube 9/55 Standard	IIb	12292
7415	Provox Life LaryTube 10/27 Standard	IIb	12292
7416	Provox Life LaryTube 10/36 Standard	IIb	12292
7417	Provox Life LaryTube 10/55 Standard	IIb	12292
7418	Provox Life LaryTube 12/27 Standard	IIb	12292

7419	Provox Life LaryTube 12/36 Standard	IIb	12292
7420	Provox Life LaryTube 12/55 Standard	IIb	12292
7421	Provox Life LaryTube 8/36 Standard with Ring	IIb	12292
7422	Provox Life LaryTube 8/55 Standard with Ring	IIb	12292
7423	Provox Life LaryTube 9/36 Standard with Ring	IIb	12292
7424	Provox Life LaryTube 9/55 Standard with Ring	IIb	12292
7425	Provox Life LaryTube 10/36 Standard with Ring	IIb	12292
7426	Provox Life LaryTube 10/55 Standard with Ring	IIb	12292
7427	Provox Life LaryTube 12/36 Standard with Ring	IIb	12292
7428	Provox Life LaryTube 12/55 Standard with Ring	IIb	12292
7429	Provox Life LaryTube 8/36, Fenestrated	IIb	12292
7430	Provox Life LaryTube 8/55, Fenestrated	IIb	12292
7431	Provox Life LaryTube 9/36, Fenestrated	IIb	12292
7432	Provox Life LaryTube 9/55, Fenestrated	IIb	12292
7433	Provox Life LaryTube 10/36, Fenestrated	IIb	12292
7434	Provox Life LaryTube 10/55, Fenestrated	IIb	12292
7435	Provox Life LaryTube 12/36, Fenestrated	IIb	12292
7436	Provox Life LaryTube 12/55, Fenestrated	IIb	12292
8040	Provox Life LaryButton 12/8	IIb	14093
8041	Provox Life LaryButton 12/18	IIb	14093
8042	Provox Life LaryButton 14/8	IIb	14093
8043	Provox Life LaryButton 14/18	IIb	14093
8044	Provox Life LaryButton 16/8	IIb	14093
8045	Provox Life LaryButton 16/18	IIb	14093
8046	Provox Life LaryButton 18/8	IIb	14093
8047	Provox Life LaryButton 18/18	IIb	14093
8048	Provox Life LaryTube 8/36 Fenestrated with Ring	IIb	12292
8049	Provox Life LaryTube 8/55 Fenestrated with Ring	IIb	12292
8050	Provox Life LaryTube 9/36 Fenestrated with Ring	IIb	12292
8051	Provox Life LaryTube 9/55 Fenestrated with Ring	IIb	12292
8052	Provox Life LaryTube 10/36 Fenestrated with Ring	IIb	12292
8053	Provox Life LaryTube 10/55 Fenestrated with Ring	IIb	12292
8054	Provox Life LaryTube 12/36 Fenestrated with Ring	IIb	12292
8055	Provox Life LaryTube 12/55 Fenestrated with Ring	IIb	12292

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

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