DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Life Adhesives

Basic UDI-DI: 7331791-ADH-0-000-0001-CT

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:
Provox Life Adhesives are single use adhesives that provide attachment for Provox Life HMEs and accessories after total laryngectomy.

Hörby, Sweden, date as stated on last page

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Henrik Heringslack, Atos Medical Site Manager
on behalf of Atos Medical AB.

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

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REF	Device name	Class*	GMDN code
7460	Provox Life Standard Adhesive Round	I	62175
7461	Provox Life Standard Adhesive Oval	I	62175
7462	Provox Life Standard Adhesive Plus	I	62175
7463	Provox Life Sensitive Adhesive Round	I	62175
7464	Provox Life Sensitive Adhesive Oval	I	62175
7466	Provox Life Sensitive Adhesive Plus	I	62175
8065	Provox Life Standard Experience Round	I	62175
8066	Provox Life Standard Experience Oval	I	62175
8067	Provox Life Standard Experience Plus	I	62175
8068	Provox Life Sensitive Experience Round	I	62175
8069	Provox Life Sensitive Experience Oval	I	62175
8070	Provox Life Sensitive Experience Plus	I	62175
8071	Provox Life Stability Experience	I	62175
8075	Provox Life Night Adhesive Experience	I	62175
8261	Provox Life Night Adhesive	I	62175
8263	Provox Life Stability Adhesive	I	62175
8095	Provox Life Adhesive Collection	I	62175

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

In compliance with UK Medical Devices Regulations 2002 as amended

Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Coloplast Limited
Nene Hall
Peterborough Business Park
Peterborough
Cambridgeshire PE2 6FX

Common Specification(s) as per Article 9, and other Union Legislation(s)

- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Approvals
Approved Date: 2026-06-16

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