DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Life LP Kit - Adhesive

Basic UDI-DI: 7331791-KIT-0-000-0006-J6

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, Article 22, Systems and procedure packs of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 7.5 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 LP Kit is an assortment of devices and accessories, intended for rehabilitation for users breathing through a tracheostoma after a total laryngectomy.

Hörby, Sweden, date as stated on last page

.....
Henrik Heringslack, AtosMedical 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		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-KIT-0-000-0006-J6

REF	Device name	Class*	GMDN code
6147	Provox Life LP Kit 18 - ADH	I	58705**

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745
**The choice of GMDN code is based on the primary product in the kit, the HME.

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 Number: VV-0623937 Status: Approved Version: 5.0
Name: DoC Provox Life LP Kit ADH. 7331791-KIT-0-000-0006-J6

Document Approvals
Approved Date: 2026-06-25

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 24-Jun-2026 06:50:04 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of RA, Voice & Respiratory Care (karolina.nilsson-atosmedical@coloplast.com) Regulatory 24-Jun-2026 08:29:11 GMT+0000

Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 25-Jun-2026 09:17:56 GMT+0000