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## DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

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### Provox FreeHands Support Adhesive

### Basic UDI-DI: 7331791-HME-A-000-0004-F8

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 FreeHands Support provides support to the Provox Adhesive when using a Provox hands-free speaking valve after total laryngectomy. The device is a single patient use device with a single use adhesive.

Hörby, Sweden, date as stated on last page

A handwritten signature in blue ink, appearing to read 'Henrik Heringslack'.

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

**Manufacturer:** **Atos Medical AB**  
Kraftgatan 8, SE-242 35 Hörby  
Sweden

Telephone: +46 (0)415 198 00  
Email: Info@atosmedical.com  
Web: www.atosmedical.com

**SRN number:** **SE-MF-000000725**

**Competent Authority** **Medical Products Agency**  
Sweden

# DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

## 7331791-HME-A-000-0004-F8

REF	Device name	Class*	GMDN code
8024	Provox FreeHands Support Adhesive (15pc)	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

Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 16-Jun-2026 14:29:22 GMT+0000
Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 16-Jun-2026 14:38:13 GMT+0000
Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 16-Jun-2026 14:52:34 GMT+0000