

# Atos

## DECLARATION OF CONFORMITY FOR THE PRODUCT(S)

### Provox Life FreeHands HME

### Basic UDI-DI: 7331791-HME-0-000-0008-XZ

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 FreeHands HME is a single use heat- and moisture exchanger intended for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and in combination with a Provox speaking valve.

Hörby, Sweden, date as stated on last page



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Henrik Heringslack, Atos Medical Site Manager  
on behalf of the CEO 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-00000725

**Competent Authority** Medical Products Agency  
Sweden

# DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

**7331791-HME-0-000-0008-XZ**

REF	Device name	Class*	GMDN code
7440	Provox Life FreeHands HME	I	58705
7477	Provox Life Sample Pack FreeHands HME	I	58705

\*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:

Atos Medical UK Ltd Tottle Road  
Cartwright House  
Nottingham  
Nottinghamshire NG2 1RT  
England, United Kingdom

#### 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: 2026-01-29

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Professional (ulrika.svensson-atosmedical@coloplast.com) Issuer 28-Jan-2026 20:27:55 GMT+0000
Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 29-Jan-2026 10:34:33 GMT+0000
Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 29-Jan-2026 16:06:46 GMT+0000