

Atos

DECLARATION OF CONFORMITY FOR THE PRODUCT(S)

Provox Tracheofix

Basic UDI-DI: 7331791-COM-0-000-0003-58

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:

The Provox Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic coverage of the tracheostoma.

Hörby, Sweden, date as stated on last page



.....
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-000000725

Competent Authority Medical Products Agency
Sweden

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-COM-0-000-0003-58

REF	Device name	Class*	GMDN code
1427	Provox Tracheofix 1 strip ivory 55x60	I	63378
1428	Provox Tracheofix 1 strip ivory 70x70	I	63378
1435	Provox Tracheofix 2 strips ivory 70x70	I	63378
1429H	Provox Tracheofix 1 strip beige 55x60	I	63378
1430H	Provox Tracheofix 1 strip beige 70x70	I	63378
1432H	Provox Tracheofix 2 strips beige 55x60	I	63378
1433H	Provox Tracheofix 2 strips beige 70x70	I	63378
1434H	Provox Tracheofix 1 strip beige 38x63	I	63378

*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: 2026-02-02

Approval Task Verdict: Approve	SOFTHO Sofia Thomasson, Regulatory Affairs Professional (sofia.thomasson-atosmedical@coloplast.com) Issuer 30-Jan-2026 10:53:55 GMT+0000
Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of RA, Voice & Respiratory Care (karolina.nilsson-atosmedical@coloplast.com) Regulatory 01-Feb-2026 16:45:39 GMT+0000
Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 02-Feb-2026 08:00:50 GMT+0000