

# Atos

## DECLARATION OF CONFORMITY FOR THE PRODUCT(S)

### Provox Brush

**Basic UDI-DI: 7331791-VPS-A-000-0003-RR**

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 Brush is used for cleaning of all Provox voice prostheses.

The Provox Brush is used for cleaning of LaryTube fenestrations.

The Provox Brush is used for application of Fluorosilicone oil in ActiValve.

The Provox Brush may be used for application of Anti-Candida medications into a voice prosthesis.

The distal end of the Provox Brush is used as insertion tool for the Provox Plug.

The Provox Brush is intended for use by the patient.

The Brush is intended for single patient re-use.

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.

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

# DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

**7331791-VPS-A-000-0003-RR**

| REF     | Device name          | Class* | GMDN code |
|---------|----------------------|--------|-----------|
| 7204    | Provox Brush         | I      | 62095     |
| 7225    | Provox Brush XL      | I      | 62095     |
| 8404    | Provox Brush Long    | I      | 62095     |
| 8404-18 | Provox Brush Long    | I      | 62095     |
| 8425    | Provox Brush Long XL | I      | 62095     |
| 8425-18 | Provox Brush Long XL | I      | 62095     |

\*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: 2026-01-26

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|-----------------------------------|--|
| Approval Task<br>Verdict: Approve | HENRIK.HERINGSLACK Henrik Heringslack, Site Director<br>(henrik.heringslack-atosmedical@coloplast.com)<br>Management<br>26-Jan-2026 13:39:38 GMT+0000        |
| Approval Task<br>Verdict: Approve | SEHRBHNU Ulrika Svensson, Regulatory Affairs Professional<br>(ulrika.svensson-atosmedical@coloplast.com)<br>Issuer<br>26-Jan-2026 13:40:36 GMT+0000          |
| Approval Task<br>Verdict: Approve | KARNIL Karolina Nilsson, Head of RA, Voice & Respiratory Care<br>(karolina.nilsson-atosmedical@coloplast.com)<br>Regulatory<br>26-Jan-2026 13:49:53 GMT+0000 |