DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Brush

Basic UDI: 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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Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO 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		

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

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Name: DoC Provox Brush 7331791-VPS-A-000-0003-RR

Document Approvals

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Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 06-Sep-2023 11:26:12 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 07-Sep-2023 12:42:14 GMT+0000