DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Dilator

Basic UDI-DI: 7331791-VPS-A-000-0011-RQ

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 1.8 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 Dilator is intended to dilate or stent the tracheoesophageal puncture in laryngectomized patients.

Hörby, Sweden, date as stated on last page

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

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SRN number:	**SE-MF-000000725**		
Notified Body:	**DNV Product Assurance AS** Identification no. 2460	**Notified Body certificate number:**	C520850

Conformity Assessment Procedure: Quality management system and on assessment of technical documentation as per Annex IX

Document Number: VV-0686419 Status: Approved Version: 2.0
Name: DoC Provox Dilator 7331791-VPS-A-000-0011-RQ

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REF	Device name	Class*	GMDN code
8341	Provox Dilator	IIa	67401

*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.

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: 2026-04-02

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