DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Life Oxygen

Basic UDI-DI: 7331791-HME-A-000-0009-FP

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:
Provox Life Oxygen is a single-use accessory to Provox Life HMEs. It allows additional oxygen supply for patients breathing through a tracheostoma using Provox Life HMEs.

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**		
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-0670865 Status: Approved Version: 1.0
Name: DoC Provox Life Oxygen 7331791-HME-A-000-0009-FP

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REF	Device name	Class*	GMDN code
7620	Provox Life Oxygen (10 pcs)	IIa	67419
7621	Provox Life Oxygen (30 pcs)	IIa	67419

*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: 2025-10-07

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