Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sofia Thomasson - SOFTHO	2022-09-14 - 11:59
Reviewed:	QA	John Wennborg - JOHWEN	2022-09-16 - 17:18
Approved:	OP	Martin Richardson - MARRIC	2022-09-16 - 18:59
Released:	QA	Ulrika Svensson - SEHRBHNU	2022-09-20 - 09:25

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® FreeHands HME®

Basic UDI: 7331791-HME-0-000-0003-XJ

We, Atos Medical AB, hereby declare under our sole responsibility that the devices listed below comply with European Medical Devices Regulation (EU) 2017/745 and clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Intended use/purpose:
Provox FreeHands HME Cassette/Moist/Flow is intended for single use for spontaneously breathing laryngectomized patients, utilizing a voice prosthesis and must be used in combination with a Provox FreeHands speaking valve, a Provox cap or DigiTop O2. Provox FreeHands combines pulmonary rehabilitation with its Heat and Moisture Exchanging functionality with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance.

Hörby, Sweden date as stated above

.....
Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer: SE-MF-000000725
Atos Medical AB, Kraftgatan 8, SE-242 35 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

Document No: 10000043731 Edition: 04 Release date: 2022-09-20
Released

DECLARATION OF CONFORMITY

7331791-HME-0-000-0003-XJ

REF	Name	Class	GMDN code
8220	Provox FreeHands HME Moist (30 pcs)	I	58705
8221	Provox FreeHands HME Flow (30 pcs)	I	58705

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.

For standards applied and valid conformity assessment certificates please contact the manufacturer.

Released
Document No: 10000043731 Edition: 04 Release date: 2022-09-20