Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Sofia Thomasson - SOFTHO	2022-09-14 - 12:08
Reviewed:	QA	John Wennborg - JOHWEN	2022-09-16 - 17:35
Approved:	OP	Martin Richardson - MARRIC	2022-09-16 - 18:53
Released:	QA	Ulrika Svensson - SEHRBHNU	2022-09-20 - 09:29

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® HME Cap™

Basic UDI: 7331791-HME-A-000-0002-F2

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 HME Cap is a single patient use, dome-shaped titanium ring, that allows use of Provox FreeHands HME cassette (REF 8220, 8221) without Provox FreeHands FlexiVoice.

Provox HME Cap is only intended for use when using Provox FreeHands FlexiVoice is not recommended, i.e. when sleeping.

Provox HME Cap cannot be used with any other type of HME cassette. The front opening of the cap can be occluded manually to speak. Provox HME Cap can be cleaned and reused.

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
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Competent Authority:
Medical Products Agency, Sweden

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DECLARATION OF CONFORMITY

7331791-HME-A-000-0002-F2

REF	Name	Class	GMDN code
7730	Provox HME Cap	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.

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