Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2021-05-18 - 16:07
Reviewed:	QA	John Wennborg - JOHWEN	2021-05-18 - 16:56
Approved:	OP	Martin Richardson - MARRIC	2021-05-18 - 17:29
Released:	QA	Ulrika Svensson - SEHRBHNU	2021-05-19 - 11:38

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

Provox® Capsule

Basic UDI: 7331791-VPS-A-000-0000-RG

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:
The Provox Capsule is a single use accessory for anterograde insertion of a standard voice prosthesis by a clinician into the tracheoesophageal puncture of laryngectomized patients.

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

Document No: 10000045920 Edition: 01 Release date: 2021-05-19
Released

DECLARATION OF CONFORMITY

7331791-VPS-A-000-0000-RG

REF	Name	Class	GMDN code
7795	Provox Capsule 17Fr	I	62134
7796	Provox Capsule 20Fr	I	62134
7797	Provox Capsule 22.5Fr	I	62134

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.

Document No: 10000045920 Edition: 01 Release date: 2021-05-19
Released