Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Ulrika Svensson - SEHRBHNU	2023-02-20 - 10:58
Reviewed:	QA	John Wennborg - JOHWEN	2023-02-20 - 21:06
Approved:	OP	Martin Richardson - MARRIC	2023-02-21 - 19:15
Released:	QA	Ulrika Svensson - SEHRBHNU	2023-02-22 - 08:18

This document has been electronically signed by the persons above.

Atos

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Protector

Basic UDI: 7331791-TEX-0-000-0001-WN

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, any other applicable Union legislation and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and, UK Medical Devices Regulations 2002, including amendments in effect at the issuance date.

Intended use/purpose:
The Provox Protector is a reusable cover that provides protection and coverage of the tracheostoma.

Hörby, Sweden. Date as stated above

.....
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**		
Competent Authority	**Medical Products Agency** Sweden		

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DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-TEX-0-000-0001-WN

REF	Device name	Class	GMDN code
7385	Provox Protector Small White	I	31065
7386	Provox Protector Large White	I	31065
7387	Provox Protector Slim Small White	I	31065
7388	Provox Protector Slim Small Blue	I	31065
7389	Provox Protector Slim Large White	I	31065
7390	Provox Protector Slim Large Blue	I	31065
7391	Provox Protector Air Small White	I	31065
7392	Provox Protector Air Small Blue	I	31065
7393	Provox Protector Air Large White	I	31065
7394	Provox Protector Air Large Blue	I	31065

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.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

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

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