Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
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This document has been electronically signed by the persons above.

DECLARATION OF CONFORMITY
MDR CLASS I

Provox® Tracheofix

Basic UDI: 7331791-COM-0-000-0003-58

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 Tracheofix is a single use foam protector intended to absorb secretions and to provide protection and aesthetic 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, P.O. Box 183, SE-242 22 Hörby, Sweden
Tel: +46 (0)415 198 00
Email: info@atosmedical.com, Web: www.atosmedical.com

Competent Authority:
Medical Products Agency, Sweden

DECLARATION OF CONFORMITY MDR CLASS I

7331791-COM-0-000-0003-58

REF	Name	Class	GMDN code
1427	Provox Tracheofix 1 strip ivory 55x60	I	63378
1428	Provox Tracheofix 1 strip ivory 70x70	I	63378
1435	Provox Tracheofix 2 strips ivory 70x70	I	63378
1429H	Provox Tracheofix 1 strip beige 55x60	I	63378
1430H	Provox Tracheofix 1 strip beige 70x70	I	63378
1432H	Provox Tracheofix 2 strips beige 55x60	I	63378
1433H	Provox Tracheofix 2 strips beige 70x70	I	63378
1434H	Provox Tracheofix 1 strip beige 38x63	I	63378

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.

Atos
atosmedical.com

Document title
Declaration of Conformity

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This document has been electronically signed by the persons above.

We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing Annex II, with the exemption of section 4 (for class IIa and class IIb devices) and Annex VII (for class I devices) of the European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The Trach Accessories

REF	Name	Class	GMDN code
1502	Stoma Oil 100ml	IIb	57897
1601	Freevent Tracheal Tube Detergent Powder	I	63385
7756	HME DigiTop O2	IIa	58705
7769	Freevent O2 Adaptor 10pcs	IIa	58705

Each kind of medical device to which the system has been applied complies with the applicable provisions of the Essential Principles and Essential Requirements, the classification rules, applicable standards and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Valid Certificates are controlled and filed by QA/RA Department. For standards applied see Applicable Standards & Essential Requirements for each product.

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Notified Body: *Intertek Semko AB, Sweden. Identification no. 0413*
EC-certificate no. 41310296-03

Competent Authority: *Medical Products Agency, Sweden*

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This document has been electronically signed by the persons above.

We, Atos Medical AB, hereby declare that the below mentioned devices comply with Swedish regulation LVFS 2003:11, transposing Annex II, with the exemption of section 4 (for class IIa and class IIb devices) and Annex VII (for class I devices) of the European Medical Devices Directive 93/42/EEC and clause 3.5 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

The Trach-HME Products

REF	Name	Class	GMDN code
7704	TrachPhone (50 pcs)	IIa	58705
7705	MEDIFLUX HCH F6 (Medival)	IIa	58705
7707	TrachPhone (30 pcs)	IIa	58705

Each kind of medical device to which the system has been applied complies with the applicable provisions of the Essential Principles and Essential Requirements, the classification rules, applicable standards and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Valid Certificates are controlled and filed by QA/RA Department. For standards applied see Applicable Standards & Essential Requirements for each product.

Notified Body: *Intertek Semko AB, Sweden. Identification no. 0413*
EC-certificate no. 41310296-03

Competent Authority: *Medical Products Agency, Sweden*

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