



DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox XtraHME

Basic UDI-DI: 7331791-HME-0-000-0000-X9

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:

The Provox XtraHME Cassette is a single use, specialized device intended for patients breathing through a tracheostoma. It is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moist from exhaled air in the device. It partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

Hörby, Sweden, date as stated on last page

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

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Competent Authority Medical Products Agency
Sweden

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REF	Device name	Class*	GMDN code
7272	Provox XtraFlow HME (20 pcs)	I	58705
7272-18	Provox XtraFlow HME (20 pcs)	I	58705
7273	Provox XtraMoist HME (20 pcs)	I	58705
7273-18	Provox XtraMoist HME (20 pcs)	I	58705
7290	Provox XtraMoist HME (30 pcs)	I	58705
7290-18	Provox XtraMoist HME (30 pcs)	I	58705
7290ES	Provox XtraMoist HME	I	58705
7291	Provox XtraFlow HME (30 pcs)	I	58705
7291-18	Provox XtraFlow HME (30 pcs)	I	58705
7291ES	Provox XtraFlow HME	I	58705
8229	Provox XtraFlow & XtraMoist HME (5+5pcs)	I	58705
8229-18	Provox XtraFlow & XtraMoist HME (5+5pcs)	I	58705

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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

Document Approvals
Approved Date: 2025-09-18

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of RA, Voice & Respiratory Care (karolina.nilsson-atosmedical@coloplast.com) Regulatory 18-Sep-2025 11:49:47 GMT+0000
Approval Task Verdict: Approve	NINROG Nina Rogelius, Regulatory Affairs Professional (nina.rogelius-atosmedical@coloplast.com) Issuer 18-Sep-2025 13:05:02 GMT+0000
Approval Task Verdict: Approve	MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 18-Sep-2025 13:46:24 GMT+0000