DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent HME 15

Basic UDI-DI: 7331791-HME-0-000-0010-XE

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:
Freevent HME 15 is a Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a ISO 15 mm connector. The HME conditions inhaled air by retaining heat and moisture from the exhaled air. The device also partially restores lost breathing resistance.

The HME is used in combination with Freevent DualCare Speaking valve/Freevent DualCare Speaking Valve Blue, with Freevent HME DigiTop/Freevent HME DigiTop Blue, or with HME DigiTop O2.

The HME is for single use, i.e. it has to be exchanged at least every 24 hours.

Hörby, Sweden, date as stated on last page

……
Henrik Heringslack, Atos Medical Site Manager
on behalf 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		

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-HME-0-000-0010-XE

REF	Device name	Class*	GMDN code
7742	Freevent HME 15 Regular (30pcs)	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:
Coloplast Limited
Nene Hall
Peterborough Business Park
Peterborough
Cambridgeshire PE2 6FX

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 Number: VV-0570833 Status: Approved Version: 5.0
Name: DoC Freevent HME 15 7331791-HME-0-000-0010-XE

Document Approvals

Approved Date: 2026-06-16

Approval Task Verdict: Approve	SOFTHO Sofia Thomasson, Regulatory Affairs Specialist (sofia.thomasson-atosmedical@coloplast.com) Issuer 16-Jun-2026 13:17:00 GMT+0000

Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 16-Jun-2026 13:22:30 GMT+0000

Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of RA, Voice & Respiratory Care (karolina.nilsson-atosmedical@coloplast.com) Regulatory 16-Jun-2026 17:58:10 GMT+0000