DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent DualCare

Basic UDI-DI: 7331791-HME-0-000-0005-XQ

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 DualCare is a combined Speaking Valve and Heat and Moisture Exchanger (HME) intended for spontaneously breathing tracheostomized patients using a tracheostomy tube with a deflated cuff, or a tracheostomy tube without cuff.

In HME-mode the device conditions inhaled air by retaining heat and moisture from the exhaled air. By turning the lid of the Speaking Valve into speaking mode air is re-directed to enable speech.

The entire device is for single patient use and the HME-part is for single use.

Hörby, Sweden, date as stated on last page

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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		

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REF	Device name	Class*	GMDN code
7740	Freevent DualCare Set 22	I	36071
7741	Freevent DualCare Set 15	I	36071
7744	Freevent DualCare Speaking Valve	I	36071
7745	Removal Aid	I	58705
7746	Freevent Connection strap	I	36071
7755	Freevent DualCare Speaking Valve Blue	I	36071

*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:
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Nene Hall
Peterborough Business Park
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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-0544273 Status: Approved Version: 10.0
Name: DoC Freevent DualCare 7331791-HME-0-000-0005-XQ

Document Approvals

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