DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Freevent Dressing

Basic UDI-DI: 7331791-COM-0-000-0001-52

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 Freevent Dressings are single use tracheal dressings that provide protection between the tracheal cannula and the skin and absorb secretions.

Hörby, Sweden, date as stated on last page

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Henrik Heringslack, Atos Medical Site Manager
on behalf of Atos Medical AB.

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SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

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REF	Device name	Class*	GMDN code
1425	Freevent Dressing AL 80x100	I	15624
14250	Freevent Dressing slt 90x100	I	15624
14251	Freevent Dressing AL slt 80x100	I	15624
14253	Freevent Dressing Combi slt 90x100	I	15624
14254	Freevent Dressing Combi AL slt 90x100	I	15624
14255	Freevent Dressing Combi 90x100	I	15624
14256	Freevent Dressing Combi AL 90x100	I	15624
14257	Freevent Dressing Combi slt 90x150	I	15624
14259	Freevent Dressing Combi 90x150	I	15624
142510	Freevent Dressing Dbl 90x100	I	15624
142511	Freevent Dressing Dbl AL 90x100	I	15624
142512	Freevent Dressing Dbl slt 90x100	I	15624
142513	Freevent Dressing Dbl AL slt 90x100	I	15624
142514	Freevent Dressing Dbl 90x150	I	15624
142515	Freevent Dressing Dbl AL slt 90x150	I	15624
142516	Freevent Dressing Dbl slt 90x150	I	15624
14250-PED	Freevent Dressing slt 65x70 PED	I	15624
14253H	Freevent Dressing Combi BG slt 90x100	I	15624
14255H	Freevent Dressing Combi BG 90x100	I	15624
14256H	Freevent Dressing Combi AL/BG 90x100	I	15624
18008-001	Freevent Dressing AL 65x70 PED	I	15624

*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

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Name: DoC Freevent Dressing 7331791-COM-0-000-0001-52

Document Approvals
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Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 23-Jun-2026 13:30:13 GMT+0000

Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 23-Jun-2026 14:03:59 GMT+0000

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