

# Atos

## DECLARATION OF CONFORMITY FOR THE PRODUCT(S)

### Freevent® Dressing

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

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**SRN number:** SE-MF-00000725

**Competent Authority** Medical Products Agency  
Sweden

# DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

**7331791-COM-0-000-0001-52**

REF	Device name	Class*	GMDN code
1425	Freeevent Dressing AL 80x100	I	15624
14250	Freeevent Dressing slt 90x100	I	15624
14251	Freeevent Dressing AL slt 80x100	I	15624
14253	Freeevent Dressing Combi slt 90x100	I	15624
14254	Freeevent Dressing Combi AL slt 90x100	I	15624
14255	Freeevent Dressing Combi 90x100	I	15624
14256	Freeevent Dressing Combi AL 90x100	I	15624
14257	Freeevent Dressing Combi slt 90x150	I	15624
14258	Freeevent Dressing Combi AL slt 90x150	I	15624
14259	Freeevent Dressing Combi 90x150	I	15624
142510	Freeevent Dressing Dbl 90x100	I	15624
142511	Freeevent Dressing Dbl AL 90x100	I	15624
142512	Freeevent Dressing Dbl slt 90x100	I	15624
142513	Freeevent Dressing Dbl AL slt 90x100	I	15624
142514	Freeevent Dressing Dbl 90x150	I	15624
142515	Freeevent Dressing Dbl AL slt 90x150	I	15624
142516	Freeevent Dressing Dbl slt 90x150	I	15624
1425921	Freeevent Trach Dressing slt 90x100	I	15624
1425923	Freeevent Trach Dressing slt 90x150	I	15624
1425932	Freeevent Dressing AL slt 90x100	I	15624
1425933	Freeevent Dressing AL slt 90x150	I	15624
14250-PED	Freeevent Dressing slt 65x70 PED	I	15624
142512-PED	Freeevent Dressing Dbl slt 65x70	I	15624
14251-PED	Freeevent Dressing AL slt 65x70	I	15624
14253H	Freeevent Dressing Combi BG slt 90x100	I	15624
14253H-PED	Freeevent Dressing Combi BG slt 65x70	I	15624
14253-PED	Freeevent Dressing Combi slt 65x70	I	15624
14255H	Freeevent Dressing Combi BG 90x100	I	15624
14256H	Freeevent Dressing Combi AL/BG 90x100	I	15624
14259H	Freeevent Dressing Combi BG slt 90x150	I	15624
18008-001	Freeevent 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:

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: 2023-12-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 11-Dec-2023 18:37:03 GMT+0000
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Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Dec-2023 08:58:28 GMT+0000