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## DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

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### Freeevent Clothing Cover

### Basic UDI-DI: 7331791-TEX-0-000-0000-WK

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 Freeevent Clothing Cover is a reusable clothing cover that provides protection and coverage of the tracheostoma.

Hörby, Sweden, date as stated on last page

A handwritten signature in blue ink, appearing to read "Henrik Heringslack".

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

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

**Competent Authority** Medical Products Agency  
Sweden

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FOR THE PRODUCT(S)

**7331791-TEX-0-000-0000-WK**

REF	Device name	Class*	GMDN code
1410A15BP	Clothing scarf, dark blue cotton/polyses	I	31065
1410A15TG	Clothing scarf, dark blue trevira-georg	I	31065
1410A1TG	Clothing scarf, blue with white dots TG	I	31065
1410A21BP	Clothing scarf, grey Cotton/Polyester	I	31065
1410A3BP	Clothing scarf, white cotton/polyester	I	31065
1410A3TG	Clothing scarf, white trevira-georgette	I	31065
1410A4BP	Clothing scarf, black cotton/polyester	I	31065
1410A4TG	Clothing scarf, black trevira-georgette	I	31065
1410A7BP	Clothing scarf, beige Cotton/Polyester	I	31065
1410A9TG	Clothing scarf speckled black'n white TG	I	31065
1413RSR1	Clothing round T-shirt w zip lock white	I	31065
1413RSR11	Clothing round neck, T-shirt, zip grey	I	31065
1413RSR2	Clothing round T-shirt w zip lock beige	I	31065
1413RSR4	Clothing T-shirt w zip lock light blue	I	31065
1413RSR8	Clothing round T-shirt w zip lock blue	I	31065
1413RSR9	Clothing round T-shirt w zip lock black	I	31065
1414RS1	Clothing round neck T-shirt form white	I	31065
1414RS5	Clothing round neck T-shirt form blue	I	31065
1414RS6	Clothing round neck T-shirt form black	I	31065

\*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 Approvals  
Approved Date: 2026-06-23

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 23-Jun-2026 13:31:54 GMT+0000
Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 23-Jun-2026 14:03:16 GMT+0000
Approval Task Verdict: Approve	KARNIL Karolina Nilsson, Head of RA, Voice & Respiratory Care (karolina.nilsson-atosmedical@coloplast.com) Regulatory 23-Jun-2026 17:54:16 GMT+0000