

Atos

DECLARATION OF CONFORMITY FOR THE PRODUCT(S)

Freeevent Clothing Stoma 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



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

Manufacturer: Atos Medical AB
Kraftgatan 8, SE-242 35 Hörby
Sweden

Telephone: +46 (0)415 198 00
Email: Info@atosmedical.com
Web: www.atosmedical.com

SRN number: SE-MF-00000725

Competent Authority Medical Products Agency
Sweden

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-TEX-0-000-0000-WK

REF	Device name	Class*	GMDN code
1400	Clothing cover White 3ply Velcro closure	I	31065
1401	Clothing cover White 4ply Velcro closure	I	31065
1402	Clothing cover White 8ply Velcro closure	I	31065
1403	Clothing cover White 12ply Velcro closure	I	31065
14001	Clothing cover Beige 3ply Velcro closure	I	31065
14011	Clothing cover Blue 4ply Velcro closure	I	31065
14012	Clothing cover Beige 4ply Velcro closure	I	31065
14022	Clothing cover Beige 8ply Velcro closure	I	31065
14023	Clothing cover Blue 8ply Velcro closure	I	31065
14033	Clothing cover Beige 12ply Velcro closure	I	31065
14034	Clothing cover Blue 12ply Velcro closure	I	31065
140011	Clothing cover blue 3ply Velcro closure	I	31065
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
1410A5BP	Clothing scarf, vine red cotton/polyest	I	31065
1410A5TG	Clothing scarf, vine red trevira-george	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
1413RSR15	Clothing round T-shirt w zip lock d.brown	I	31065
1413RSR2	Clothing round T-shirt w zip lock beige	I	31065
1413RSR3	Clothing round T-shirt w zip lock yellow	I	31065
1413RSR4	Clothing T-shirt w zip lock light blue	I	31065
1413RSR6	Clothing round T-shirt w zip lock red	I	31065
1413RSR7	Clothing round T-shirt w zip lock d.green	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
1414RS2	Clothing round neck T-shirt form beige	I	31065
1414RS3	Clothing round T-shirt form light blue	I	31065
1414RS4	Clothing round neck green	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.

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-TEX-0-000-0000-WK

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: 2026-02-13

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Professional (ulrika.svensson-atosmedical@coloplast.com) Issuer 13-Feb-2026 08:33:59 GMT+0000
Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 13-Feb-2026 14:42:34 GMT+0000
Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 13-Feb-2026 14:49:59 GMT+0000