

evercare[®] Surgical cap Tricolor

REF: 2770-01

evercare[®] Tricolor features a wide sweatband that surrounds the whole head, providing optimal sweat absorption and comfort. The very popular cap is chosen for its comfortable design with sweatband. Made in a soft and breathable viscose nonwoven material (100% fossil-free), it also provides plenty of room for long hair. Universal size and elastic in the back to provide a secure fit. The use of headwear is proven to reduce the risk of particles falling into the surgical wound. Fits wall dispenser REF 2700

Key Features:

- ▶ Reduces the risk of particles falling into the wound
- ▶ Suits all wearers, regardless of size or hairstyle
- ▶ Wide sweat band around the head
- ▶ Good coverage also for long hair
- ▶ Elastic in the back
- ▶ Universal size
- ▶ Fits wall dispenser REF 2700



REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
2770-01	Surgical cap Tricolor, white/ blue/green disposable	Universal	50/300

Sales Unit: Transport Carton

Technical Summary

Regulations

The product complies with legal requirements for medical devices



REACH regulation:	The product(s) covered by this data sheet does(do) not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).
Biological evaluation:	EN ISO 10993-10
Compliance with legal requirements:	Medical Device Regulation (EU) 2017/745, Class I
Compliance with product standards:	N/A
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN 1041

Material

Product Part	Raw Material & Characteristic
Forehead and tail cap	Viscose nonwoven, green
Top cap	Viscose nonwoven, blue
Sweatband	Viscose spunlance nonwoven, white
Elastic band	Polyester yarn & Synthetic rubber, latex free, white
Sewing threads	Nylon, white

Warnings and Recommendations

Warnings:	The product is single use. If reused performance of product may deteriorate, cross contamination may occur.
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.
Disposal Recommendation	Dispose in accordance with local regulations.
Shelf Life	5 Years

Packing Information

Package	Material	Size (L x W x H) mm
Single Pack	N/A	N/A
Dispenser Pack	Carton, TCF or ECF quality	185 x 300 x 145
Transport Carton	Carton, TCF or ECF quality	385 x 310 x 455
Packing Tape	Transparent, PVC-free	N/A

Barcodes

REF	Single Pack	Dispenser	Transport Carton
2770-01	N/A	 6 438129 319644	 6 438129 519648



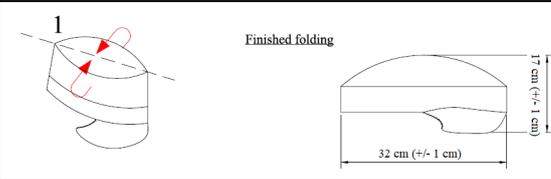
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 FI-00321 Helsinki, Finland
 Phone +358 20 786 6800
 www.onemed.com
 Domicile Helsinki
 Business ID 2039640-1

TUOTE-ERITTELY / PRODUCT SPECIFICATION

Tuotteen kuvaus / Description of the product
Surgical cap Tricolor, white/blue/green disposable (Ref. 2770-01)

Tuotteen käyttötarkoitus / Intended use of the product
A head covering intended to be worn by surgical staff during an operation to protect both the patient and the operating room personnel from transfer of micro-organisms, body fluids, and particulate material.

Raaka-aineet / Raw materials

Tuotteen osa/ product part	Raaka-aine / Raw material	Lisätiedot / Additional information
Nonwoven	Spunlace CV (viscose) nonwoven	
Elastic band	CV/PET (viscose/polyester) nonwoven Latex-free	6 cm wide
Sewing thread	Nylon	
Dispenser box	TCF	Size 14,5x18,5x30 cm (HxWxL), 310g/m ² , white with OneMed printing on it
Transport carton	TCF	Size 45,5x31x38,5 cm (HxWxL), white with OneMed printing on it
Transport carton label	Coated paper	Size 210x120 mm, OneMed printing
Packing tape	Transparent, PVC-free	

Tuotteen laatuvaatimukset / Quality specifications of the product

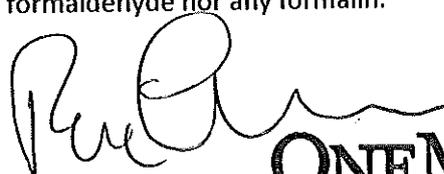
Ominaisuus / Characteristic (yksikkö / dimension)	Tavoitearvo / Target value	Laaturajat / Quality tolerances	Testimenetelmä / Test method
Product measurements and other details	see attached drawings	see attached drawings	Measuring
Loose particles, dirt, dust and holes.	None allowed	Must be removed in production.	Visual inspection.
Sewing thread ends	≤ 1,0 cm	Max. 1,0 cm	Visual inspection
Sewing quality	a) Density of stitches not too big. b) no break ups beside the seams	a) When cover is stretched elastic band is not coming loose b) not allowed	a) Manual & visual inspection b) Visual inspection

Tuotteen valmistusmenetelmät / Manufacturing methods of product

Valmistus vaihe / Production step	Vaatus / requirement
Laying and cutting	Product must be cut to size which is defined in product drawings. Cutting must be neat.
Sewing	When cap is stretched elastic band is not coming loose.
Packing	See attached packing instructions given in enclosed drawing pages
Labelling	See separate label specifications for labelling instructions.

2013-01-25
Gothenburg
Peter Jonason

I hereby certify that none of the masks inside the attached product catalogue contain any formaldehyde nor any formalin.


Peter Jonason

ONEMED
Sverige AB

Category Manager Surgical and Wound Care

ONEMED

Encl. 1 Version 2012 product catalogue for caps and masks

Encl. 2 Investigation report from the mask supplier; Thai Hospital.



Surgical masks and caps



Professional protection by evercare®

Surgical masks are intended to be worn by health care professionals during surgery. They should be worn at other times to catch the bacteria shed in liquid droplets and aerosols from the wearer's mouth and nose.

European Standard EN 14683 specifies the construction and performance requirements, and test methods for surgical masks intended to limit the transmission of infective agents from staff to patients and (in certain situations vice-versa) during surgical procedures in operating theatres and other medical settings with similar requirements.

Key requirements of EN14683

1. Bacterial Filtration Efficiency

Determination of the filtration efficiency of the face mask. The higher the BFE %, the better the protection.

Classification: BFE = ≥ 95 % TYPE I
BFE = ≥ 98 % TYPE II

2. Breathing Resistance

Determination of the airflow resistance of the surgical mask. The lower the differential pressure, the higher the breathing comfort.

Classification: TYPE I & II (non splash resistant) = < 29.4 Pa/cm²
TYPE IR & IIR (splash resistant) = < 49.0 Pa/cm²

3. Splash Resistance

Determination of the resistance of the mask of potentially contaminated fluid splashes.

Classification: TYPE I & TYPE II not applicable
TYPE IR & TYPE IIR >120 mmHg*

*120 mmHg is a minimum value.

It corresponds to the average systolic arterial blood pressure, and intends to protect against ruptures in small arteries causing small sprays of blood.

evercare® surgical mask assortment includes a selection of Type II and Type IIR surgical masks.

evercare® surgical masks complies to the EN14683:2005 for surgical masks.

evercare® surgical masks are soft, comfortable and provide excellent fit.



Surgical masks and caps
Surgical hoods



**Surgical hood Gallant,
shoulder protection**

Patterned viscose
nonwoven, latex-free

REF 2779

Green
Pack count: 6 x 50



**Surgical hood Valiant,
shoulder protection**

Patterned viscose
nonwoven, latex-free

REF 2780

Blue
Pack count: 6 x 50



**Surgical hood Lancelot,
neck protection**

Patterned viscose
nonwoven, latex-free

REF 2785

Green
Pack count: 6 x 50



**Surgical hood James,
tie-on**

Patterned viscose nonwoven,
latex-free

REF 2773

Green
Pack count: 6 x 100



REF 2774

Blue
Pack count: 6 x 100

Surgical caps



Surgical cap Tricolor

Patterned viscose nonwoven, soft spunlace sweatband, latex-free

REF 2770

Green/blue/white

Pack count: 6 x 50



Surgical cap Romeo

Patterned viscose nonwoven, latex-free

REF 2788

Green

Pack count: 6 x 100



Surgical cap Kolumbus

Patterned viscose nonwoven, latex-free

REF 2776

Green

Pack count: 6 x 100



Surgical cap Tristan, tie-on

Patterned viscose nonwoven, latex-free

REF 2791

Green

Pack count: 6 x 100



Surgical cap Kolumbus

Patterned viscose nonwoven, latex-free

REF 2777

Blue

Pack count: 6 x 100



Surgical cap Tina

Patterned viscose nonwoven, latex-free

REF 2782

Green

Pack count: 6 x 100



Surgical cap Kolumbus

Patterned viscose nonwoven, latex-free

REF 2778

Violet

Pack count: 6 x 100



Surgical cap Tina

Patterned viscose nonwoven, latex-free

REF 2783

Blue

Pack count: 6 x 100

Surgical caps



Round cap Rondo Standard

Polypropylene nonwoven, latex-free

Pack count: 6 x 150

REF 2740

M (48 cm) Green

REF 2741

M (48 cm) White

REF 2742

M (48 cm) Blue

REF 2743

M (48 cm) Pink

REF 2744

M (48 cm) Multicolor
(Green/Blue/Pink)



REF 2750

L (52 cm) Green

REF 2751

L (52 cm) White



REF 2752

L (52 cm) Blue

REF 2753

L (52 cm) Pink

REF 2754

L (52 cm) Multicolor
(Green/Blue/Pink)

REF 2760

XL (55 cm) Green



Rondo Special

Polypropylene nonwoven, latex-free

REF 2765

L (52 cm) Blue

Pack count: 6 x 150



REF 2761

XL (55 cm) White

REF 2762

XL (55 cm) Blue

REF 2763

XL (55 cm) Pink

REF 2764

XL (55 cm) Multicolor
(Green/Blue/Pink)



Rondo Extra

Polypropylene nonwoven, latex-free

REF 2766

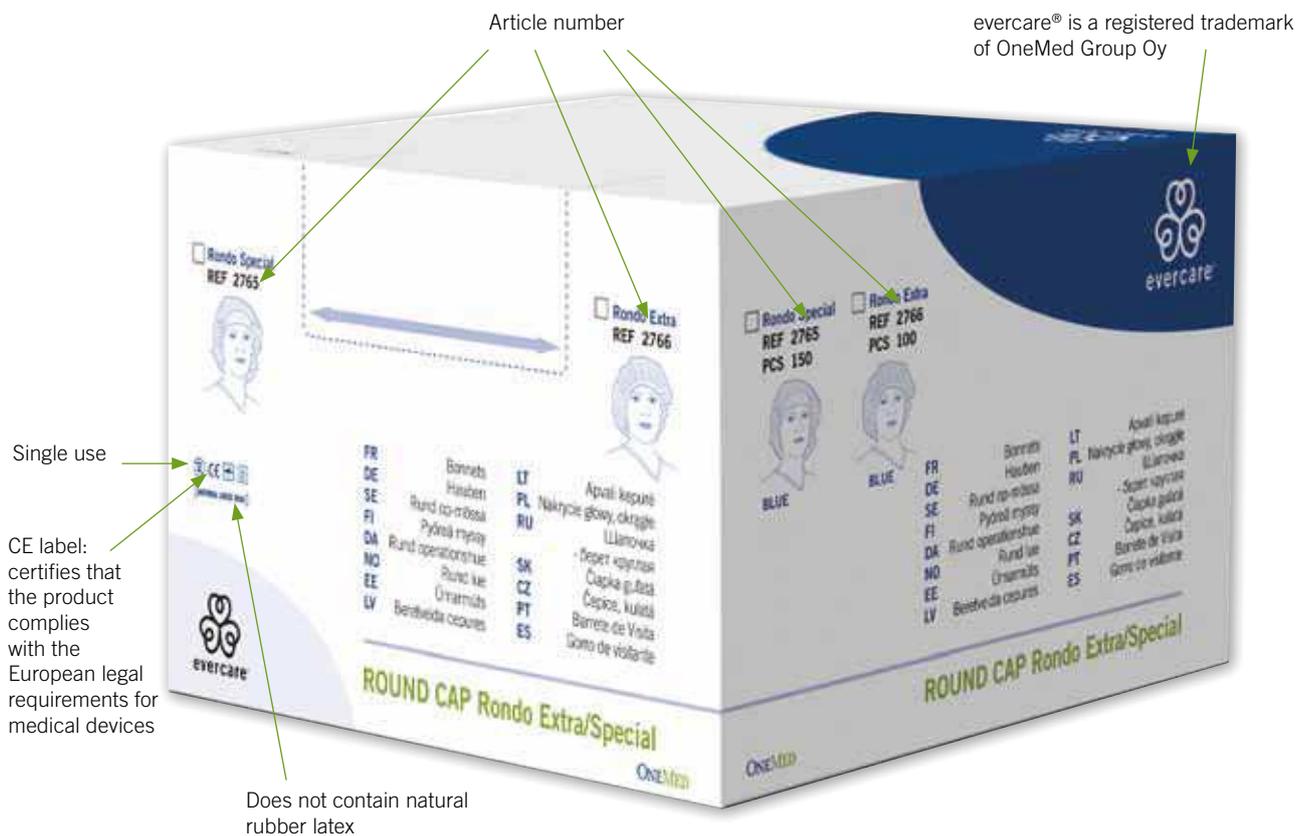
L (52 cm) Blue

Pack count: 6 x 100

Surgical masks and caps

Label information in accordance with EN ISO 15223-1 and EN 1041

Surgical masks and caps



DECLARATION OF CONFORMITY

replaces version dated: 23.04.2020

We

OneMed Group Oy, Metsäläntie 20, FI-00320 Helsinki

declare under our sole responsibility that following products, all belonging to class I according to Annex IX of the Directive 93/42/EEC for medical devices,

Name, type or model:

2740, 2740-01, 2740-02	Round cap Rondo standard, size M, green
2741, 2741-01, 2741-02	Round cap Rondo standard, size M, white
2742, 2742-01, 2742-02	Round cap Rondo standard, size M, blue
2743, 2743-01, 2743-02	Round cap Rondo standard, size M, pink
2744, 2744-01, 2744-02	Round cap Rondo Multicolour standard, size M, green/blue/pink
2750, 2750-01, 2750-02	Round cap Rondo standard, size L, green
2751, 2751-01, 2751-02	Round cap Rondo standard, size L, white
2752, 2752-01, 2752-02	Round cap Rondo standard, size L, blue
2753, 2753-01, 2753-02	Round cap Rondo standard, size L, pink
2754, 2754-01, 2754-02	Round cap Rondo Multicolour standard, size L, green/blue/pink
2760, 2760-01, 2760-02	Round cap Rondo standard, size XL, green
2761, 2761-01, 2761-02	Round cap Rondo standard, size XL, white
2762, 2762-01, 2762-02	Round cap Rondo standard, size XL, blue
2763, 2763-01, 2763-02	Round cap Rondo standard, size XL, pink
2764, 2764-01, 2764-02	Round cap Rondo Multicolour standard, size XL, green/blue/pink
2765	Round cap Rondo Special, blue
2766	Round cap Rondo Extra, blue
2767	Round cap, Rondo Special, blue size XL
2770, 2770-01	Surgical cap Tricolor white/blue/green
2776, 2776-01	Surgical cap Kolumbus, green
2777, 2777-01	Surgical cap Kolumbus, blue
2778, 2778-01	Surgical cap Kolumbus, violet
2782, 2782-01	Surgical cap Tina, green
2783, 2783-01	Surgical cap Tina, blue
2784, 2784-01	Surgical cap Julia for long hair, violet
2788, 2788-01	Surgical cap Romeo, green
2791, 2791-01	Surgical cap Tristan, green
2794, 2794-01	Surgical cap Lady, green
270050	evercare® Round cap Rondo Basic, size L, blue
270051	evercare® Round cap Rondo Basic, size XL, blue
270052	evercare® Round cap Rondo, size L, blue
270053	evercare® Round cap Rondo, size XL, blue

to which this declaration relates, are in conformity with the provisions of the laws of Finland and with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC of 5 September 2007 and with all applicable harmonized standards¹:

EN ISO 13485

Medical Devices – Quality management systems – Requirements for regulatory purposes

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EN ISO 14971 Medical Devices – Application of risk management to medical devices
EN 1041 Information supplied by the manufacturer with medical devices
EN ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements

List of other than harmonized standards applied in the production?:

-

^{1,2}Latest revisions of regulations and standards in document Review of regulations and standards

Place and date of issue

Malmö 22.06.2020

Name and signature of the authorized person

Julien Rolland
Sourcing Director