

evercare<sup>®</sup> XP Standard OP-Gowns, sterile

REF: 2504, 2505, 2507, 2509, 2510, 2513, 2514, 2515, 2517, 2519, 2520

evercare<sup>®</sup> XP Standard OP-Gowns are suitable for dry operations. Made in a soft SMS material with antistatic and alcohol repellent treatment for enhanced user protection. All evercare<sup>®</sup> OP-Gowns provide an effective barrier to body fluids, skin particles and microbes and are designed for optimal comfort and ease of movement. The adjustable Velcro in the neck enables optimal fit while securing adjustments. High quality cuffs for improved comfort and tight fit round wrists. The gown is sterilized with EO-gas and packed in easy-to-open unit pouches. State-of-the-art packaging system with handy functional dispenser and labelling. Unit packs are supplied with barcoded removable labels for improved traceability.

## Key Features

- ▶ Good protection and Xtra comfort, antistatic and alcohol repellent treated
- ▶ Ultrasonic heat sealed seams for sleeves and shoulders to increase comfort by reducing excessive materials causing discomfort
- ▶ Gown with overlapping back and adjustable Velcro in the neck enables optimal fit for individual adjustments.
- ▶ Clear stamp with size and performance type.
- ▶ High quality cuffs for improved comfort and tight fit round wrists.
- ▶ Belt card with clear indications of sterile / non-sterile for secure donning.
- ▶ Book-folding enabling unpacking and donning without risk for contamination.
- ▶ SMS material with low linting and very high abrasion resistance



REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
2504	XP Standard OP-Gown, sterile, Blue	Size M-short, Length 120 cm	21 / 42
2505	XP Standard OP-Gown, sterile, Blue	Size M, Length 131 cm	20 / 40
2507	XP Standard OP-Gown, sterile, Blue	Size L, Length 142 cm	20 / 40
2509	XP Standard OP-Gown, sterile, Blue	Size XL, Length 152 cm	18 / 36
2510	XP Standard OP-Gown, sterile, Blue	Size XXL, Length 160 cm	18 / 36
2513	XP Standard OP-Gown with hand towels, sterile, Blue	Size XXL-Long, Length 170 cm	14 / 28
2514	XP Standard OP-Gown with hand towels, sterile, Blue	Size M-short, Length 120 cm	21 / 42
2515	XP Standard OP-Gown with hand towels, sterile, Blue	Size M, Length 131 cm	20 / 40
2517	XP Standard OP-Gown with hand towels, sterile, Blue	Size L, Length 142 cm	20 / 40
2519	XP Standard OP-Gown with hand towels, sterile, Blue	Size XL, Length 152 cm	18 / 36
2520	XP Standard OP-Gown with hand towels, sterile, Blue	Size XXL, Length 160 cm	18 / 36

Sales Unit: Transport Carton

# Regulations

The product complies with legal requirements for medical devices. EO sterilized according to valid version of ISO 11135 standard.



**REACH regulation:** The products covered by this data sheet 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).

<b>Biological evaluation:</b>	EN ISO 10993-5 EN ISO 10993-7 EN ISO 10993-10
<b>Compliance with legal requirements:</b>	Medical Device Regulation (EU) 2017/745, MDR Class Is
<b>Compliance with product standards:</b>	EN ISO 11135, EN 13795-1 Standard performance
<b>Quality standards:</b>	EN ISO 13485
<b>Label information and packaging compliance:</b>	EN ISO 20417, EN ISO 11607-1, EN ISO 15223-1

# Material

Product Part	Raw Material & Characteristics
Body, sleeve, belt	PP SMS nonwoven, blue
Cuff	PES, rib knitted fabric
Neck ribbon	PP Spunbond nonwoven, white
Velcro band	PA woven ribbon with hook or loop
Belt card	Cellulose pulp (ECF), white
Wrapping crepe	Pulp (ECF), white
Sewing thread	PES, white
Hand towel	2pcs, Scrim Reinforced Tissue, white

## Warnings & Recommendations

<b>Warnings</b>	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
<b>Storage Recommendation</b>	Recommended storage in clean, dry space between 15 - 25 °C. Products should be protected from direct sunlight, other intensive light sources and ozone.
<b>Disposal Recommendation</b>	Dispose in accordance with local regulations.
<b>Shelf Life</b>	5 years

## Packaging Information

<b>Package</b>	<b>Material</b>	<b>Size ( L x W x H ) mm</b>
<b>Single Pack</b>	Medical grade paper, PP/PE film	242 x 334
<b>Dispenser Pack</b>	Carton, TCF or ECF quality	381 x 279 x 320
<b>Transport Carton</b>	Carton, TCF or ECF quality	574 x 401 x 330
<b>Packing Tape</b>	PVC-free, Transparent	N/A

## Barcodes / UDI-DI

REF	Single Pack	Dispenser Pack	Transport Carton
2504	06438129112139	06438129312133	06438129512137
2505	06438129112146	06438129312140	06438129512144
2507	06438129112153	06438129312157	06438129512151
2509	06438129112160	06438129312164	06438129512168
2510	06438129112177	06438129312171	06438129512175
2513	06438129124293	06438129324297	06438129524291
2514	06438129112184	06438129312188	06438129512182
2515	06438129112191	06438129312195	06438129512199
2517	06438129112207	06438129312201	06438129512205
2519	06438129112214	06438129312218	06438129512212
2520	06438129112221	06438129312225	06438129512229

Evercare Medical AB is a partner that enables better lives for patients, facilitates everyday life for healthcare employees and contributes to lower care costs. We strive to reduce the environmental impact and, together with our suppliers, to improve working conditions throughout the value chain.

# Statement

*evercare® XP Standard OP-Gowns sterile*

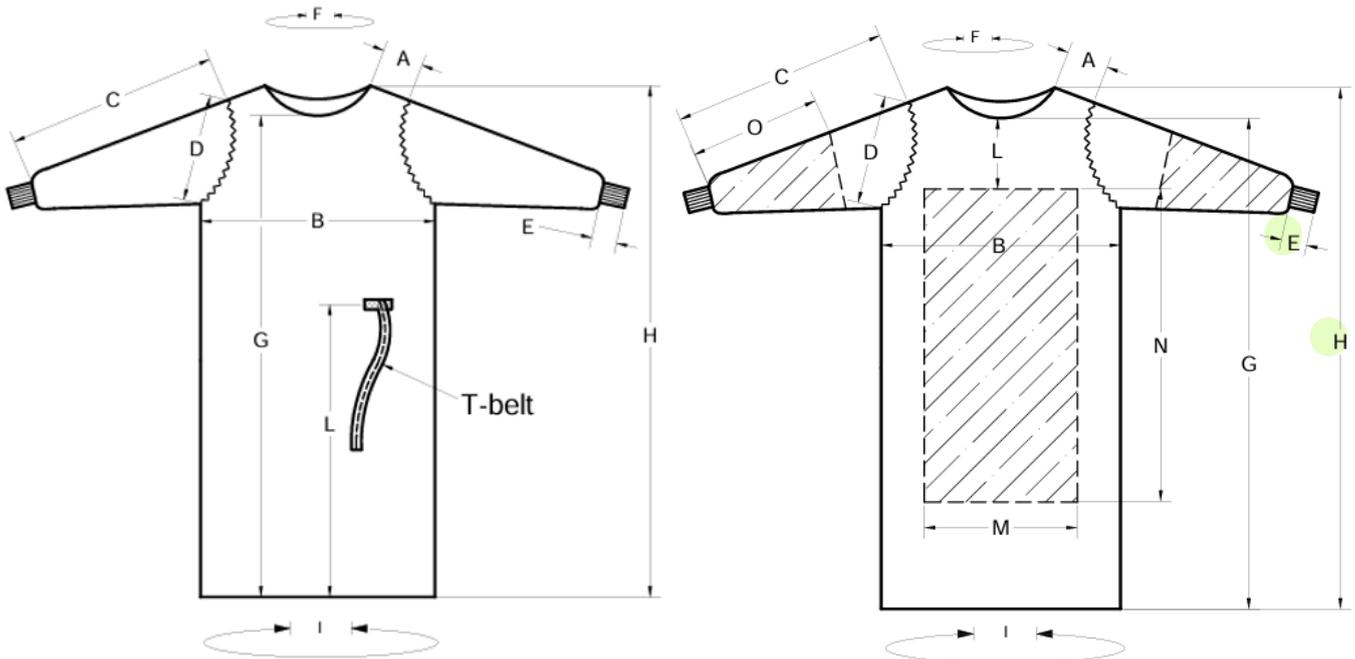
*evercare® XP Special OP-Gowns sterile*

To whom it may concern

The statement refers to following surgical gowns:

REF	Product Name
2504	evercare® XP Standard OP-gown, size M-short
2505	evercare® XP Standard OP-gown, size M
2507	evercare® XP Standard OP-gown, size L
2509	evercare® XP Standard OP-gown, size XL
2510	evercare® XP Standard OP-gown, size XXL
2513	evercare® XP Standard OP-gown with hand towels, size XXL-long
2514	evercare® XP Standard OP-gown with hand towels, size M-short
2515	evercare® XP Standard OP-gown with hand towels, size M
2517	evercare® XP Standard OP-gown with hand towels, size L
2519	evercare® XP Standard OP-gown with hand towels, size XL
2520	evercare® XP Standard OP-gown with hand towels, size XXL
2534	evercare® XP Special OP-gown, size M-short
2535	evercare® XP Special OP-gown, size M
2537	evercare® XP Special OP-gown, size L
2539	evercare® XP Special OP-gown, size XL
2540	evercare® XP Special OP-gown, size XXL
2544	evercare® XP Special OP-gown with hand towels, size M-short
2545	evercare® XP Special OP-gown with hand towels, size M
2547	evercare® XP Special OP-gown with hand towels, size L
2549	evercare® XP Special OP-gown with hand towels, size XL
2550	evercare® XP Special OP-gown with hand towels, size XXL

**Finished Drawing**



All measurements given in "cm".

SIZE							
REF	2504&2514	2505&2515	2507&2517	2509&2519	2510&2520	2513	TOL.
	2534/2544	2535/2545	2537/2547	2539/2549	2540/2550		

Size	M-S	M	L	XL	XXL	XXL-long	TOL.
A shoulder width	19.5	19.5	21	25	25	25	±2
B chest	66.5	66.5	68	72.5	80.5	80.5	±2
C sleeve	56	56	59	63	64	64	±2
D sleeve width	28	28	32.5	33	35	35	±2
E cuff	7	7	7	7	7	7	±1.5
F collar	64	64	65	67	69	69	±2
G front collar to bottom	112	123	133	143	145	157	±2
H shoulder point to bottom	120	131	142	152	160	170	±2
I bottom	152	152	160	174	178	178	±3
J loop	10	10	15	15	15	15	±1
K hook	3.5	3.5	7	7	7	7	±1
L belt to bottom	73.5	85.5	94.5	102	103	103	±1

15

The values for the reinforcement measurements M, N, O:

M	Front reinforcement, width	40	40	50	50	50	N/A	±2
N	Front reinforcement, length	65	70	80	90	95	N/A	±2
O	Sleeve reinforcement	39	39	41	43	45	N/A	±2

The truthfulness of the information given in this statement verified.

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2024-10-23



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Nurodyta pagaminimo vieta ir galiojimas





# EU Quality Management System Certificate

Certificate no.:  
10000510540-PA-NoMA-DNK

Initial certification date:  
18 May 2022

Valid Until:  
18 May 2027

This is to certify that the quality system of

**ONEMED GROUP OY**

Metsäläntie 20  
00320 HELSINKI  
Finland

For design, production and final product inspection/testing of:

Sterile Fixation bandages, Sterile support bandages, sterile gauze swabs and sponges, sterile nonwoven swabs and sponges, sterile absorbent dressings, sterile applicators, sterile surgical gowns, sterile drapes, sterile tube holders.

Has been assessed and found to comply with respect to:

**The conformity assessment procedure described in Annex IX,  
(Chapter I) of Regulation (EU) 2017/745 on Medical Devices**

Place and date:  
Høvik, 17 October 2022



For the issuing office:  
DNV Product Assurance AS – Notified Body 2460  
Veritasveien 1, 1363 Høvik, Norway

**Hazem Tinawi**  
Management Representative

### Jurisdiction

Application of Regulation 2017/745 on medical devices, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

### Certificate history:

Revision	Description	Report No.	Issue Date
0.0	Original Certificate	2623081, 2623077, 2623082	18 May 2022
1.0	Add devices marked in bold	2745294	15 July 2022
2.0	Admin change	2720384	12 October 2022
3.0	Admin change	Not applicable	17 October 2022

### Products covered by this Certificate:

Product Description	Product Name	Class*
<b>Sterile single use medical devices</b>	Applicators, sterile Absorbent dressings, sterile Fixation bandages, sterile Support bandages, sterile Swabs and Sponges, gauze, sterile Swabs and Sponges, nonwoven, sterile Surgical Gowns, sterile Instrument and Equipment drapes, sterile Surgical drapes, sterile Tube holders, sterile	Class Is

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

Site Name	Address
OneMed Group Oy	Metsäläntie 20, 00320 Helsinki, Finland
Evercare Medical AB	Tagenevägen 29, Box 50, SE-401 20 Göteborg, Sweden

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.
- For the class III devices covered this certificate is dependent on the continued validity of the EU Technical Documentation Assessment Certificate, covering the devices.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window

## Specific conditions - Class I devices, Systems and Procedure Packs:

- For class I device being placed on the market in a sterile condition, Class I devices with a measurement function and class I devices being reusable surgical instruments covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 52(7) of the regulation.
- For system and procedure packs being placed on the market in a sterile condition, covered by this certificate the audit by the notified body of the quality management system was limited to the aspects required under article 22(3) of the regulation.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EU declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.