Product Data Sheet

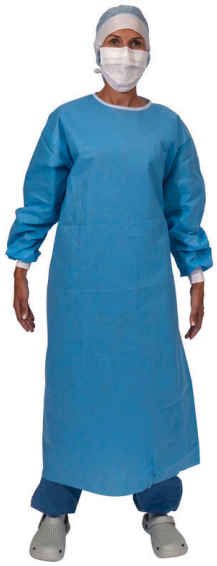
SELEFA® Essentia Reinforced Surgical Gown, sterile

REF: 255203, 255303, 255403, 255503

SELEFA® Essentia Reinforced Surgical Gown is suitable for the procedures with medium to high-qantity of fluids. Made from soft antistatic SMS nonwoven material, this gown adheres to EN 13795-1 requirements for high performance and provides an effective barrier against body fluids, skin particles and microbes while insuring comfort and ease of movement. SELEFA® Essentia Reinforced gown is reinforced with a breathable material in the critical zones, in the front and in the sleeves, to maximize protection against contamination of the surgical wound and to protect the user at wet procedures. The adjustable Velcro in the neck enables optimal fit while securing adjustments. High quality cuffs for improved comfort and tight fit. The gown is sterilized with EO-gas and packed in easy-to-open unit pouche. Our state-of-the-art packaging system with handy functional dispenser and labelling, meets all standard requirements. The Unit pack is supplied with barcoded removable labels for improved traceability.

Key Features

- Antistatic treated nonwoven material
- High breathability and abrasion resistance
- Laminated reinforcement for critical areas on front and sleeves
- SMS nonwoven with low linting
- Ultrasonic heat sealed seams for sleeves and shoulders
- Gown with overlapping back and adjustable Velcro in the neck
- Clear stamp with size and performance type
- Belt card with clear indication of sterile / non-sterile for secure donning
- High quality cuffs for comfort and tight fit
- Wrapping in envelope from SPP material as well as book-folding enables secure unpacking and donning

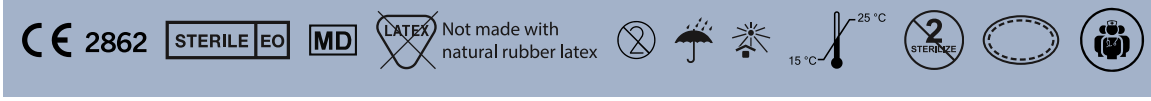


REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
255203	SELEFA® Essentia Reinforced Surgical Gown,sterile, Blue	M	20 / 40
255303	SELEFA® Essentia Reinforced Surgical Gown,sterile, Blue	L	18 / 36
255403	SELEFA® Essentia Reinforced Surgical Gown,sterile, Blue	XL	16 / 32
255503	SELEFA® Essentia Reinforced Surgical Gown,sterile, Blue	XXL	16 / 32

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

Material

Product Part	Raw Material & Characteristics
Body, Sleeve, Belt	PP SMS nonwoven
Reinforcement sleeve and front	PP Spunbond / PE laminated
Neck ribbon	PP Spunbond nonwoven, white
Cuff	PES, rib knitted fabric, white
Velcro band	PA woven ribbon with hook or loop
Belt card	Cellulose pulp (ECF)
Wrapping drape	PP Spunbond nonwoven, blue
Sewing thread	PES, white
Hand towel	Scrim reinforced tissue, white

Warnings & Recommendations

Warnings	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
Storage Recommendation	Recommended storage in clean, dry space between 15 - 25 °C. 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

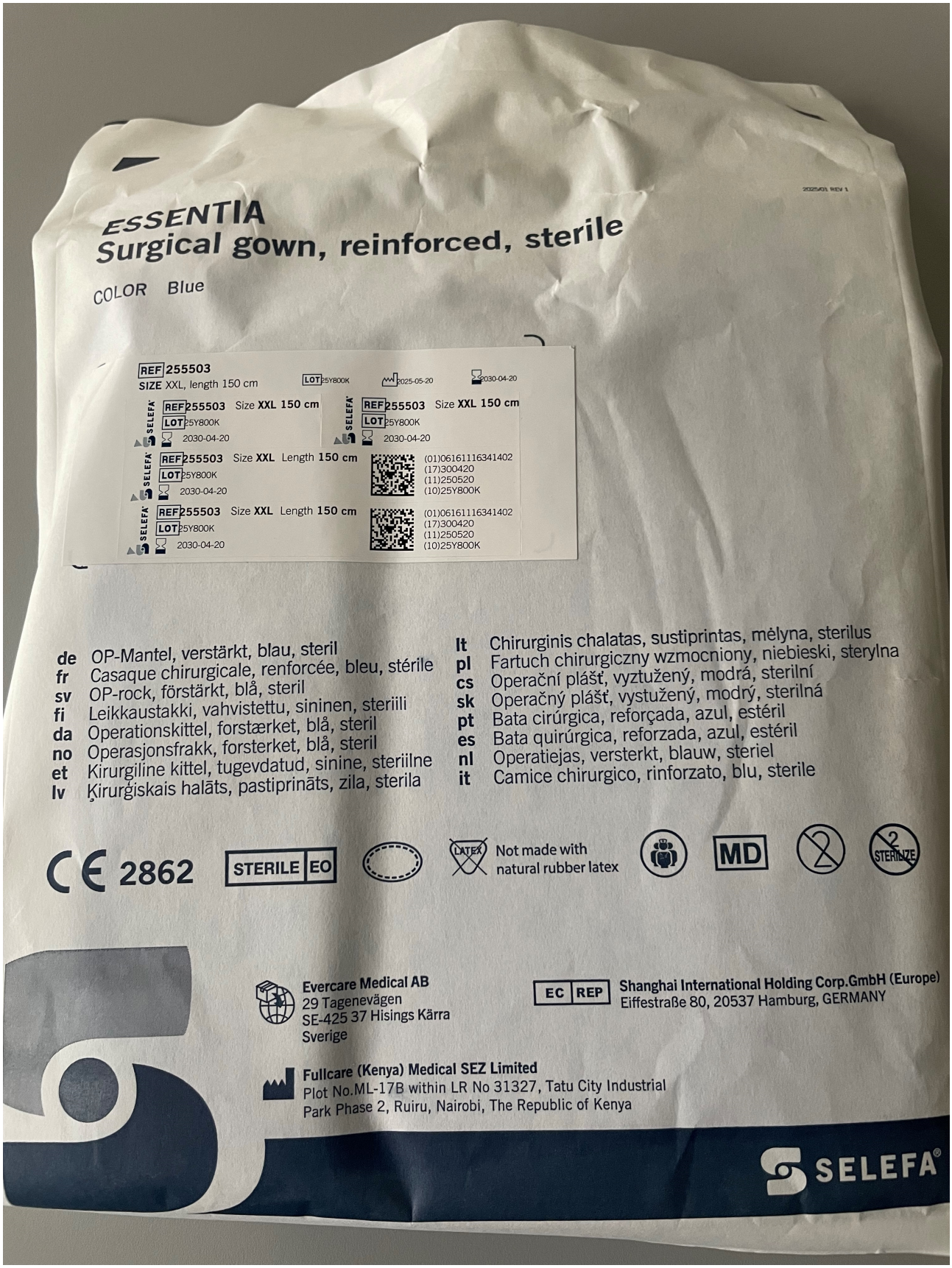
Packaging Information

Package	Material	Size (L x W x H) mm
Single Pack	Medical grade paper, PA/PE	255203: 225 x 298 x 30 255303: 225 x 298 x 30 255403: 242 x 334 x 30 255503: 242 x 334 x 30
Dispenser Pack	Cardboard, TCF or ECF quality	381 x 279 x 370
Transport Carton	TCF or ECF quality, Carton	574 x 401 x 380
Packing Tape	PVC-free, Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser Pack	Transport Carton
255203	06161116341136	06161116341143	06161116341150
255303	06161116341228	06161116341235	06161116341242
255403	06161116341310	06161116345691	06161116345707
255503	06161116341402	06161116341419	06161116341426

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.


ESSENTIA
Surgical gown, reinforced, sterile
COLOR Blue
REF 255503
SIZE XXL, length 150 cm
LOT 25Y800K
2025-05-20
2030-04-20
REF 255503 Size XXL 150 cm
LOT 25Y800K
2030-04-20
REF 255503 Size XXL Length 150 cm
LOT 25Y800K
2030-04-20
(01)06161116341402
(17)300420
(11)250520
(10)25Y800K
de OP-Mantel, verstärkt, blau, steril
fr Casaque chirurgicale, renforcée, bleu, stérile
sv OP-rock, förstärkt, blå, steril
fi Leikkaustakki, vahvistettu, sininen, steriili
da Operationskittel, forstærket, blå, steril
no Operasjonsfrakk, forsterket, blå, steril
et Kirurgiline kittel, tugevdatud, sinine, steriilne
lv Ķirurģiskais halāts, pastiprināts, zila, sterila
lt Chirurginis chalatas, sustiprintas, mėlyna, sterilus
pl Fartuch chirurgiczny wzmocniony, niebieski, sterylna
cs Operační plášť, vyztužený, modrá, sterilní
sk Operačný plášť, vystužený, modrý, sterilná
pt Bata cirúrgica, reforçada, azul, estéril
es Bata quirúrgica, reforzada, azul, estéril
nl Operatiejas, versterkt, blauw, steriel
it Camice chirurgico, rinforzato, blu, sterile
CE 2862
STERILE EO
LATEX Not made with natural rubber latex
MD
2 STERILIZE
Evercare Medical AB
29 Tagenevägen
SE-425 37 Hisings Kärra
Sverige
EC REP Shanghai International Holding Corp.GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY
Fullcare (Kenya) Medical SEZ Limited
Plot No.ML-17B within LR No 31327, Tatu City Industrial
Park Phase 2, Ruiru, Nairobi, The Republic of Kenya
SELEFA

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

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*
Sterile single use medical devices	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.