

# evercare® Optimia Special OP-gowns, sterile

REF: 2576-01, 2577-01, 2578-01, 2579-01, 2580-01

evercare® Optimia Special OP-gown is a SMS gown designed to provide ultimate protection and high comfort. The gown aim to provide a cost-efficient alternative to the traditional gowns made of cotton like fabrics. These gowns provide an effective barrier to body fluids and microbes. The surgical gown is designed for optimal comfort and offers ease of movement with overlapping material in the back. The large sized adjustable Velcro in the neck enables great fit for secure adjustments. High quality cuffs for improved comfort. State-of-the-art packaging system with handy functional dispenser and labeling as per EN15223-1 and EN1041. Barcoded removable labels for improved traceability. The gown is sterilized in EO-gas and packed in separate sterile easy-to-open packs. evercare® Optimia is available in Standard (Standard Performance) and Special (High Performance) variants and complies with the requirements of EN13795. evercare® Optimia Special is reinforced with a breathable material in the critical zone, in the front and in the sleeves, to maximize protection against contamination of the surgical wound and to protect the user at wet procedures.

## Key Features:

- Soft SMS material with antistatic and alcohol repellent treatment
- Ergonomic design in shoulders for freedom of movement
- Special product variant is suitable for wet operations / orthopedics
- Ultrasonic heat sealed seams for sleeves & shoulders
- Special product variant with breathable reinforcement
- Long arms to provide comfort and reduce tensions
- Large size adjustable Velcro strap at the neck
- Belts positioned to improve comfort
- Gown with widely overlapping back
- ▶ All sizes available with or without 2 hand towels



| REF     | DESCRIPTION   | SIZE      | PACK COUNT dispenser/carton |
|---------|---|-----------|-----------------------------|
| 2576-01 | Optimia Special OP-gown with hand towels, sterile, blue | M - short | 18/36                       |
| 2577-01 | Optimia Special OP-gown with hand towels, sterile, blue | М         | 16/32                       |
| 2578-01 | Optimia Special OP-gown with hand towels, sterile, blue | L         | 16/32                       |
| 2579-01 | Optimia Special OP-gown with hand towels, sterile, blue | XL        | 14/28                       |
| 2580-01 | Optimia Special OP-gown with hand towels, sterile, blue | XXL       | 14/28                       |

Sales Unit: Transport Carton

# **Technical Summary**

### Regulations

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

















**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)

EN ISO 10993-05, EN ISO 10993-07, EN ISO 10993-10

**Biological evaluation:** 

Compliance with legal requirements:

Medical Devices Directive 93/42/EEC, Class Is

**Compliance with product** standards:

EN ISO 11135, EN 13795 Standard performance

**Quality standards:** 

EN ISO 13485

Label information and packaging compliance:

EN ISO 15223-1, EN 1041, EN ISO 11607-1

#### **Material**

| Material                       |   |
|--------------------------------|---|
| Product Part                   | Raw Material & Characteristic           |
| Body, sleeve, belt             | PP SSMMMS nonwoven, blue                |
| Reinforcement sleeve and front | PP nonwoven / breathable PE-film, white |
| 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                     | Scrim Reinforced Tissue, white          |

## **Warnings and Recommendations**

The product is single use. If reused performance of product may deteriorate, cross conta-Warnings: mination 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 Vears   |  |

# **Packing Information**

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

### **Barcodes**

| Burocaco |                 |                 |                  |
|----------|-----------------|-----------------|------------------|
| REF      | Single Pack     | Dispenser       | Transport Carton |
| 2576-01  | 6 438129 123586 | 6 438129 323580 | 6 438129 523584  |
| 2577-01  | 6 438129 123593 | 6 438129 323597 | 6 438129 523591  |
| 2578-01  | 6 438129 123609 | 6 438129 323603 | 6 438129 523607  |
| 2579-01  | 6 438129 123616 | 6 438129 323610 | 6 438129 523614  |
| 2580-01  | 6 438129 123623 | 6 438129 323627 | 6 438129 523621  |



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