





## evercare<sup>®</sup> Surgical swabs, X-ray detectable, gauze, sewn, sterile REF: 3217-01, 3218-01, 3219-01, 3220-01

evercare<sup>®</sup> Surgical swabs, X-ray detectable, gauze, sewn, sterile are high quality surgical swabs of gauze. They have color coding for easy product identification and numeric control system for counting assistance. The control system contains following information: color code, REF number, dry weight of the product, number of individual swabs, size of individual swabs, material, and control batch number. As part of the production process the products are counted and controlled by a metal detector and the material is vacuumed to minimize loose threads. Includes extra nonwoven pouch under the sterile barrier, to allow aseptic technique when taking out from the pouch and keeping the products in place.

### Key Features

- ▶ X-ray detectable
- ▶ Sterilized with EO
- ▶ Numeric control system
- ▶ Colour coding system for easy product identification
- ▶ Wrapped into a sealed lint-free easy-to-open wrap
- ▶ High absorbency
- ▶ X-ray detectable thread safely welded to the gauze
- ▶ PVC- and phthalate-free X-ray detectable thread
- ▶ Sewn edges

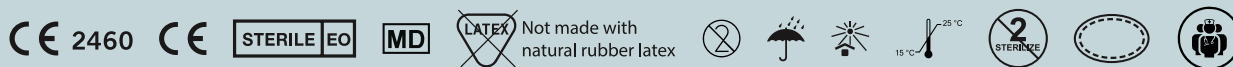


REF	DESCRIPTION	COLOR CODING	SIZE	Pack Count dispenser/carton
3217-01	Surgical swabs, X-ray detectable, gauze, sewn, 4-ply, 5-pack, sterile, Purple		10 x 60 cm	120 / 720
3218-01	Surgical swabs, X-ray detectable, gauze, sewn, 8-ply, 5-pack, sterile, Green		10 x 60 cm	65 / 390
3219-01	Surgical swabs, X-ray detectable, gauze, sewn, 12-ply, 5-pack, sterile, Red		10 x 60 cm	50 / 300
3220-01	Surgical swabs, X-ray detectable, gauze, sewn, 12-ply, 5-pack, sterile, Orange		10 x 10 cm	100 / 600

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 10993-5  
EN ISO 10993-7  
EN ISO 10993-10  
EN ISO 10993-11

**Compliance with legal requirements:** Medical Device Regulation (EU) 2017/745, MDR class IIa

**Compliance with product standards:** EN ISO 11135, EN 14079

**Quality standards:** EN ISO 13485

**Label information and packaging compliance:** EN ISO 15223-1, EN ISO 20417, EN ISO 11607-1

## Material

Product Part	Raw Material & Characteristics
Gauze	100 % cotton, 17 threads / cm <sup>2</sup> , white
X-ray detectable thread	PP, DEHP-free, PVC-free, Phthalate free X-ray thread (with barium sulphate), black
Sewing thread	100% cotton, white
Inner wrap	PP spunbond nonwoven, blue

## Warnings & Recommendations

<b>Warnings</b>	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur. Control the amount of items before use. If the amount is different than stated on the packaging, do not use the product.
<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

## Packing Information

Package	Material	Size ( L x W x H ) mm
<b>Single Pack</b>	Medical grade paper, PP/PE film	3217-01: 150 x 280 3218-01: 150 x 280 3219-01: 150 x 280 3220-01: 150 x 185
<b>Dispenser Pack</b>	Carton, TCF or ECF quality	3217-01: 273 x 155 x 250 3218-01: 273 x 155 x 250 3219-01: 273 x 155 x 250 3220-01: 185 x 155 x 250
<b>Transport Carton</b>	Carton, TCF or ECF quality	3217-01: 285 x 520 x 480 3218-01: 285 x 520 x 480 3219-01: 285 x 520 x 480 3220-01: 262 x 570 x 325
<b>Packing Tape</b>	PVC-free, Transparent	N/A

## Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
<b>3217-01</b>	06438129119473	06438129319477	06438129519471
<b>3218-01</b>	06438129119480	06438129319484	06438129519488
<b>3219-01</b>	06438129119497	06438129319491	06438129519495
<b>3220-01</b>	06438129119503	06438129319507	06438129519501

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.