

evercare® Surgical swabs, X-ray detectable, gauze, sterile

REF: 3213-01, 3214-01, 3215-01

evercare® Surgical swabs, X-ray detectable, gauze, sterile 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
- ▶ All edges are safely folded and sewn before final swab folding to minimize loose thread
- ▶ Lot number on each control card
- ▶ Easy to peel open the unit pack



REF	DESCRIPTION	COLOR CODING	SIZE	Pack Count dispenser/carton
3213-01	Surgical swab, X-ray detectable, 4-ply, 5-pack, sterile, Purple		10 x 60 cm	120 / 720
3214-01	Surgical swab, X-ray detectable, 8-ply, 5-pack, sterile, Green		10 x 60 cm	65 / 390
3215-01	Surgical swab, X-ray detectable, 12-ply, 5-pack, sterile, Red		10 x 60 cm	50 / 300

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 14079, EN ISO 11135
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 / cm², 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

Warnings	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.
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

Packing Information

Package	Material	Size (L x W x H) mm
Single Pack	Medical grade paper, PP/PE film	150 x 280
Dispenser Pack	Carton, TCF or ECF quality	273 x 140 x 310
Transport Carton	Carton, TCF or ECF quality	285 x 640 x 440
Packing Tape	PVC-free, Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
3213-01	06438129122220	06438129322224	06438129522228
3214-01	06438129122237	06438129322231	06438129522235
3215-01	06438129122244	06438129322248	06438129522242

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.