

evercare[®] Abdominal swabs, X-ray detectable, gauze, sterile





REF: 3310-01, 3311-01, 3312-01, 3316-01

evercare[®] Abdominal 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. These swabs are high quality 4-layer abdominal swabs of gauze. 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 nonwoven
- ▶ PVC- and phthalate-free X-ray detectable thread

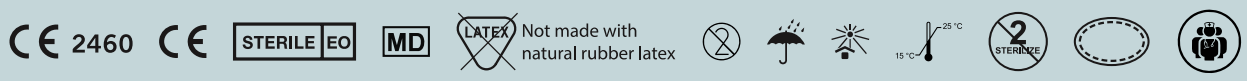


REF	DESCRIPTION	COLOR CODING	SIZE	Pack Count dispenser/carton
3310-01	Abdominal swabs, X-ray detectable, gauze, 5-pack, sterile, Brown		30 x 45 cm	55 / 330
3311-01	Abdominal swabs, X-ray detectable, gauze, single pack, sterile, Grey		45 x 70 cm	22 / 132
3312-01	Abdominal swabs, X-ray detectable, gauze, 5-pack, sterile, Black		45 x 70 cm	25 / 150
3316-01	Abdominal swabs, X-ray detectable, gauze, 5-pack, sterile, Blue		40 x 45 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 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, 20 threads / cm ² , 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 250
Transport Carton	Carton, TCF or ECF quality	285 x 520 x 440
Packing Tape	PVC-free, Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
3310-01	06438129120202	06438129320206	06438129520200
3311-01	06438129120219	06438129320213	06438129520217
3312-01	06438129120226	06438129320220	06438129520224
3316-01	06438129120233	06438129320237	06438129520231

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.