

SELEFA® Vaginal tampon X-ray detectable, sterile

REF: 222080

SELEFA® Vaginal tampon X-ray detectable, sterile is manufactured of gauze material fulfilling the requirements in standard EN 14079, increasing their absorbent properties and softness. Produced from environmental friendly bleached cotton fibres. The special cotton sling allows easy removal from the OP-field. Designed for use during outpatient procedures to control bleeding and absorb large amounts of fluids, to manage and prevent primary postpartum haemorrhage after Caesarean delivery.

Key Features

- ▶ Woven edges prevent loose threads drawing
- ▶ 100% cotton gauze
- ▶ Sterilized with EO
- ▶ Peroxide bleached gauze
- ▶ X-ray detectable thread inter-woven into gauze
- ▶ No wadding content
- ▶ Extremely high absorbent properties
- ▶ Extra strong cotton sling ensuring easy removal
- ▶ Woven in density of 17 threads/cm²

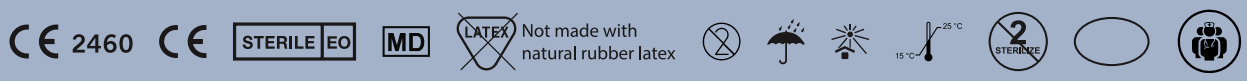


REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
222080	Vaginal tampon X-ray detectable, sterile, White	Ø 55 mm	25 / 100

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 ² , white
X-ray detectable thread	PP, DEHP-free, PVC-free, Phthalate free X-ray thread (with barium sulphate), blue
Loop – draw string	100% cotton, white

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	98 x 116
Dispenser Pack	Carton, TCF or ECF quality	128 x 102 x 330
Transport Carton	Carton, TCF or ECF quality	290 x 385 x 225
Packing Tape	PVC-free, Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
222080	06438129154597	06438129354591	06438129554595

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.