

# SELEFA® Optimia Gauze round sponges

REF: 222021, 222022, 222023, 222024

SELEFA® Optimia Gauze round sponges, non-sterile are highly absorbent sponges for a wide area of use such as: skin cleansing, wound cleansing, wiping, fluid and moisture absorption, protection, disinfection etc. Good absorbent properties and in compliance with EN 14079 to assure high quality cotton gauze. The compact folding keeps the product shape stable.

## **Key Features**

- ▶ 100% cotton gauze
- ▶ Environmental friendly bleached (no chlorine)
- Can be sterilized using EO
- ▶ 17 threads per cm2



REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
222021	Optimia Gauze round sponges, non-sterile, White	Ø 30 mm	200 / 3600
222022	Optimia Gauze round sponges, non-sterile, White	Ø 40 mm	150 / 2700
222023	Optimia Gauze round sponges, non-sterile, White	Ø 50 mm	100 / 1800
222024	Optimia Gauze round sponges, non-sterile, White	Ø 65 mm	100 / 1400

Sales Unit: Transport Carton

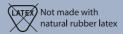
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## Regulations

The product complies with legal requirements for medical devices.















**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 10993-10

Compliance with legal requirements:

Medical Device Regulation (EU) 2017/745, MDR class I

Compliance with product standards:

EN 14079

Other tests performed:

0

**Quality standards:** 

EN ISO 13485

Label information and packaging compliance:

EN ISO 15223-1, EN ISO 20417

#### **Material**

Product Part	Raw Material & Characteristics	
Main material	100 % cotton gauze, white	
Elastic ring	Silicone-based elastic	

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## Warnings & Recommendations

warnings	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.			
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. 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	N/A	N/A
Dispenser Pack	PE bag, Transparent	222021: 270 x 390 x 104 222022: 270 x 390 x 0 222023: 270 x 390 222024: 400 x 500 x 0
Transport Carton	Carton, TCF or ECF quality	222021: 395 x 290 x 420 222022: 395 x 290 x 420 222023: 395 x 290 x 540 222024: 395 x 290 x 540
Packing Tape	PVC-free, Transparent	N/A

## Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
222021	N/A	06438129354065	06438129554069
222022	N/A	06438129354072	06438129554076
222023	N/A	06438129354089	06438129554083
222024	N/A	06438129354096	06438129554090

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.