

## SELEFA<sup>®</sup> Optimia Gauze round sponges

REF: 222021, 222022, 222023, 222024

SELEFA<sup>®</sup> 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 cm<sup>2</sup>



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

## Regulations

The product complies with legal requirements for medical devices.



<b>REACH regulation:</b>	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).
<b>Biological evaluation:</b>	EN ISO 10993-5 EN ISO 10993-10
<b>Compliance with legal requirements:</b>	Medical Device Regulation (EU) 2017/745, MDR class I
<b>Compliance with product standards:</b>	EN 14079
<b>Other tests performed:</b>	0
<b>Quality standards:</b>	EN ISO 13485
<b>Label information and packaging compliance:</b>	EN ISO 15223-1, EN ISO 20417

## Material

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

## Warnings & Recommendations

<b>Warnings</b>	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
<b>Storage Recommendation</b>	Recommended storage in clean, dry space in ambient temperature. 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
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.

## DECLARATION OF CONFORMITY

Replaces version dated:  
**31.03.2023**

Valid until the issue of next  
version of this document.

We,

**OneMed Group Oy,**  
Metsäläntie 20,  
FI-00320 Helsinki, Finland,

SRN FI-MF-000000642,

Domicile Helsinki,  
Business ID 2039640-1,

declare under our sole responsibility that following products are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and its corrigenda on May 2019 and on December 2019.

### Classification:

**Class I** according to Annex VIII of the Regulation (EU) 2017/745

### Intended Purpose:

Swabs and sponges non-sterile, are single use patches made from gauze primarily designed to cleaning, or to absorb fluids or exudates from wounds and body-surface.  
Intended Users are Health Care Professionals.

There is no restriction to a specific patient population.

The product is non-sterile.

The product intended for single use.

Duration of product use is short term contact (no more than 30 days).

### List of devices under Basic UDI-DI 6438129B0015H7:

REF	Product name
222001	SELEFA <sup>®</sup> Optimia Gauze swabs 5 x 5 cm, 8-ply
222002	SELEFA <sup>®</sup> Optimia Gauze swabs 7,5 x 7,5 cm, 8-ply
222003	SELEFA <sup>®</sup> Optimia Gauze swabs 10 x 10 cm, 8-ply
222004	SELEFA <sup>®</sup> Optimia Gauze swabs 10 x 20 cm, 12-ply
222005	SELEFA <sup>®</sup> Optimia Gauze swabs 10 x 10 cm, 16-ply
222301	SELEFA <sup>®</sup> Optimia Gauze squares 15 x 15 cm
222302	SELEFA <sup>®</sup> Optimia Gauze squares 20 x 20 cm
222303	SELEFA <sup>®</sup> Optimia Gauze squares 30 x 30 cm
222304	SELEFA <sup>®</sup> Optimia Gauze squares 40 x 40 cm
222305	SELEFA <sup>®</sup> Optimia Gauze squares 50 x 50 cm
22219512	SELEFA <sup>®</sup> Gauze swabs 5 x 5 cm, 12-ply, non-sterile
22219513	SELEFA <sup>®</sup> Gauze swabs 5 x 5 cm, 8-ply, non-sterile
22219523	SELEFA <sup>®</sup> Gauze swabs 7,5 x 7,5 cm, 12-ply, non-sterile
22219524	SELEFA <sup>®</sup> Gauze swabs 7,5 x 7,5 cm, 8-ply, non-sterile
22219534	SELEFA <sup>®</sup> Gauze swabs 10 x 10 cm, 12-ply, non-sterile
22219535	SELEFA <sup>®</sup> Gauze swabs 10 x 10 cm, 8-ply, non-sterile
22219545	SELEFA <sup>®</sup> Gauze swabs 10 x 20 cm, 12-ply, non-sterile
22219546	SELEFA <sup>®</sup> Gauze swabs 10 x 20 cm, 8-ply, non-sterile

List of devices under Basic UDI-DI 6438129B0016H9:

REF	Product name
222021	SELEFA <sup>®</sup> Optimia Gauze round sponges, diam. 30 mm
222022	SELEFA <sup>®</sup> Optimia Gauze round sponges, diam. 40 mm
222023	SELEFA <sup>®</sup> Optimia Gauze round sponges, diam. 50 mm
222024	SELEFA <sup>®</sup> Optimia Gauze round sponges, diam. 65 mm
222041	SELEFA <sup>®</sup> Optimia triangular gauze sponges 30 x 30 x 30 mm
222051	SELEFA <sup>®</sup> Optimia Flat gauze sponges 8 x 8 mm
222052	SELEFA <sup>®</sup> Optimia Flat gauze sponges 30 x 30 mm
222253	SELEFA <sup>®</sup> Gauze round sponges, diam. 30 mm
222256	SELEFA <sup>®</sup> Gauze round sponges, diam. 70 mm

These items are in conformity with following European standards and common specifications<sup>1</sup>:

EN ISO 13485	Medical Devices – Quality management systems requirements for regulatory purposes
EN ISO 14971	Medical Devices – Application of risk management
EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels – Part 1: General requirements
EN ISO 20417	Medical Devices – Information to be supplied by the manufacturer
EN 62366-1	Medical Devices – Part 1: Application of usability engineering to medical devices
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management
EN 14079	Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

<sup>1</sup>Latest applied revisions of regulations, standards and common specifications are presented in *T-079 Review of regulations and standards*

Place and date of issue

Helsinki, 21.11.2023

Name and signature of the authorized person

Regulatory Manager  
OneMed Group Oy