

Gauze round sponges, 5-pack, sterile

REF: 22225030, 22225040, 22225050, 222254

SELEFA® Gauze round sponges, sterile are high quality gauze sponges intended for a wide area of use, when sterile product state is required: pre-operative skin cleansing, wound cleansing, drying, fluid absorption etc.



Key Features:

- ▶ 100% cotton gauze
- ▶ Peroxide bleaching (no chlorine)
- ▶ Skin and wound cleansing
- ▶ Fluid absorption
- ▶ Sterilized by EO-gas treatment



| REF | DESCRIPTION | SIZE | PACK COUNT dispenser/carton |
|----------|------------------------------|---------|-----------------------------|
| 22225030 | Gauze round sponges, sterile | Ø 30 mm | 75/1500 |
| 22225040 | Gauze round sponges, sterile | Ø 40 mm | 75/1350 |
| 22225050 | Gauze round sponges, sterile | Ø 50 mm | 50/900 |
| 222254 | Gauze round sponges, sterile | Ø 70 mm | 100/800 |

Sales Unit: Transport Carton

Technical Summary

Regulations

The product complies with legal requirements for medical devices
EO sterilized according to valid version of ISO 11135.



REACH regulation: The product(s) covered by this data sheet does(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 and EN ISO 10993-10

Compliance with legal requirements: Medical Devices Directive 93/42/EEC, Class Is

Compliance with product standards: EN 14079

Quality standards: EN ISO 13485

Label information and packaging compliance: EN ISO 11607-1, EN ISO 15223-1 and EN 1041

Material

| Product Part | Raw Material & Characteristic |
|---------------|--|
| Main material | 100 % cotton gauze, white |
| Elastic ring | SEBS - Silicone Elastomer Blends, Latex free |

Warnings and Recommendations





| | |
|--------------------------------|---|
| Warnings: | The product is single use. If reused performance of product may deteriorate, 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 | Medical paper / Plastic film PA/PE/PP | 22225030: 100 x 116 |
| | | 22225040: 133 x 135 |
| | | 22225050: 133 x 135 |
| | | 222254: 133 x 135 |

| | | |
|-------------------------|----------------------------|---------------------------|
| Dispenser Pack | Carton, ECF or TCF quality | 22225030: 115 x 95 x 140 |
| | | 22225040: 130 x 130 x 150 |
| | | 22225050: 130 x 130 x 150 |
| | | 222254: 260 x 135 x 250 |
| Transport Carton | Carton, ECF or TCF quality | 22225030: 290 x 200 x 590 |
| | | 22225040: 400 x 400 x 310 |
| | | 22225050: 400 x 400 x 310 |
| | | 222254: 530 x 280 x 510 |
| Packing Tape | Transparent, PVC-free | N/A |

Barcodes

| REF | Single Pack | Dispenser | Transport Carton |
|----------|--|---|--|
| 22225030 |  6 438129 151138 |  6 438129 351132 |  6 438129 551136 |
| 22225040 |  6 438129 151145 |  6 438129 351149 |  6 438129 551143 |
| 22225050 |  6 438129 151152 |  6 438129 351156 |  6 438129 551150 |
| 222254 |  6 438129 151374 |  6 438129 351378 |  6 438129 551372 |



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