

SELEFA® Examination Gloves, Vinyl REGULAR, Phthalate-Free REF: 210286XS, 210286S, 210286M, 210286L, 210286XL

Powder-free and phthalate-free vinyl examination glove for single use.

Key Features

- Ambidextrous and with rolled rim for extra cuff strength
- ▶ Phthalate-free, powder-free and latex-free
- ▶ Good alternative to those suffering from type I and accelerator related type IV allergies



Recommendations for use







Basic cleaning

Basic procedures and wards

Wash

| REF | DESCRIPTION | SIZE CODE | Overall Length | Pack Count dispenser/carton |
|----------|--|--------------|-------------------|-----------------------------|
| 210286XS | Examination Gloves, Vinyl REGULAR, Phthalate-Free, XS, Clear | | 240 mm | 100 / 1000 |
| 210286\$ | Examination Gloves, Vinyl REGULAR, Phthalate-Free, S, Clear | | 240 mm | 100 / 1000 |
| 210286M | Examination Gloves, Vinyl REGULAR, Phthalate-Free, M, Clear | | 240 mm | 100 / 1000 |
| 210286L | Examination Gloves, Vinyl REGULAR, Phthalate-Free, L, Clear | | 240 mm | 100 / 1000 |
| 210286XL | Examination Gloves, Vinyl REGULAR, Phthalate-Free, XL, Clear | | 240 mm | 100 / 1000 |

Sales Unit: Transport Carton

Page 1 2023-12-05

Regulations

The product complies with legal requirements for medical devices.













| REACH re | egulation: |
|----------|------------|
|----------|------------|

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).

Freedom of holes: **AQL** 1.5

Force at break (N): ≥ 3.6 N (before and after challenge test)

Total quantity of powder residues for powder-free glove: < 2 mg/glove

Biological evaluation: Cytotoxicity tested acc. to EN ISO 10993-5

Irritation and skin sensitization tested acc. to EN ISO 10993-10

Compliance with legal requirements:

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

Compliance with product standards:

EN 455: 1 - 4

Food safety:

In accordance with EU Regulations 1935/2004 and 10/2011 the glove is suitable for handling all foodstuffs except fatty foods.

Other tests performed:

Viral penetration according to ASTM F1671

Quality standards:

EN ISO 13485

Label information and packaging compliance:

EN ISO 15223-1, EN ISO 20417

Material

| Product Part | Raw Material & Characteristics | |
|--------------|--|--|
| Palm | Polyvinyl Chloride, single wall thickness min. 0.05 mm | |
| Finger | Polyvinyl Chloride, single wall thickness min. 0.07 mm | |

Page 2 2023-12-05

Warnings & Recommendations

| Warnings | The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur. | | | |
|------------------|--|--|--|--|
| Storage Recommen | dation Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone. | | | |
| Disposal Recomme | ndation 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 | Cardboard, TCF or ECF quality | 240 x 120 x 60 |
| Transport Carton | Corrugated board, TCF or ECF quality | 320 x 250 x 250 |
| Packing Tape | PVC-free, Transparent | N/A |

Barcodes / UDI-DI

| REF | Single Pack | Dispenser | Transport Carton |
|----------|-------------|----------------|------------------|
| 210286XS | N/A | 06438129353877 | 06438129553871 |
| 210286S | N/A | 06438129353884 | 06438129553888 |
| 210286M | N/A | 06438129353891 | 06438129553895 |
| 210286L | N/A | 06438129353907 | 06438129553901 |
| 210286XL | N/A | 06438129353914 | 06438129553918 |

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.