# Severcare

## evercare<sup>®</sup> Examination Gloves, Nitrile SVEA REF: 6415, 6416, 6417, 6418, 6419

Nitrile examination glove and protective glove for single use, blue/lilac.

## Key Features

- Powder-free, ambidextrous and with rolled rim for extra cuff strength.
- Excellent tactile sensitivity and enhanced wet and dry grip with micro-textured finger tips.
- Excellent fit, easy to don and remove.
- Well recognized examination glove color for ward.
- Higher quality with AQL 1.0 of pinholes for safer use.
- Very good viral barrier properties, protects against a wide variety of chemicals.
- Free of latex and proteins, good alternative to those suffering from type I allergies.

#### Recommendations for use





Sales Unit: Transport Carton



## Regulations

| The product complies with le        | egal requirements for medical devices and personal protective equipments.<br><b>LATEX FREE</b> $\bigotimes$ $\stackrel{\text{EN ISO 374-52016}}{\longrightarrow}$ $\bigotimes$ $\bigotimes$ $\bigvee$                 |  |  |
|-------------------------------------|---|--|--|
| 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 Candidate List published by European Chemicals Agency (ECHA). |  |  |
| Freedom of holes:                   | AQL 1.0   |  |  |
| Force at break (N):                 | $\geq$ 6.0 N (before and after challenge test)  |  |  |
| Biological evaluation:              | Cytotoxicity tested acc. to EN ISO 10993-5<br>Irritation and skin sensitization tested acc. to EN ISO 10993-10  |  |  |
| Compliance with legal requirements: | Medical Device Regulation (EU) 2017/745, MDR class I<br>Personal Protective Equipment Regulation (EU) 2016/425, PPE R category III. EU<br>Declaration of Conformity for Personal Protective Equipment: https://www.evercare-<br>medical.com/about-us  |  |  |
| Compliance with product standards:  | EN 455: 1 – 4   |  |  |
| Chemical Resistance:                | Tested in accordance with EN 16523-1  |  |  |
| Food safety:                        | In accordance with EU Regulation 1935/2004 the glove is suitable for handling al foodstuffs.  |  |  |
| Other tests performed:              | Air leak and Water leak according to EN 374-2 (Level 2)<br>Chemicals residue<br>Dexterity, length and pH according to EN 420<br>Mechanical performance according to EN 388<br>Microbiological quality<br>RoHS compliance<br>Resistance to degradation by chemicals according to EN 374-4                        |  |  |

|   | Viral penetration according to EN 374-5 and ASTM F1671 |  |  |
|---|--|--|--|
| Quality standards:                          | EN ISO 13485   |  |  |
| Label information and packaging compliance: | EN ISO 15223-1 EN ISO 20417 EN 420                     |  |  |

## Material

| Product Part | Raw Material & Characteristics  |  |
|--------------|---|--|
| Palm         | Acrylonitrile-butadiene (Nitrile), single wall thickness min. 0.07 mm |  |
| Finger       | Acrylonitrile-butadiene (Nitrile), single wall thickness min. 0.10 mm |  |

## Warnings & Recommendations

| Warnings                | contamina | e product is single use. If reused, the performance of product may deteriorate and cross<br>atamination may occur.<br>e product contains dithiocarbamates – not to be used in case of hypersensitivity to these<br>ostances. |  |  |
|-------------------------|-----------|--|--|--|
| 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   | Cellulose, TCF quality | 240 x 120 x 75        |  |
| Transport Carton | Cellulose, TCF quality | 385 x 250 x 250       |  |
| Packing Tape     | PVC-free, Transparent  | N/A                   |  |

#### Barcodes / UDI-DI

| REF  | Single Pack | Dispenser      | Transport Carton |
|------|-------------|----------------|------------------|
| 6415 | N/A         | 06438129313109 | 06438129513103   |
| 6416 | N/A         | 06438129313116 | 06438129513110   |
| 6417 | N/A         | 06438129313123 | 06438129513127   |
| 6418 | N/A         | 06438129313130 | 06438129513134   |
| 6419 | N/A         | 06438129313147 | 06438129513141   |

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.