

# Examination gloves, Nitrile SVEA

REF: 6415, 6416, 6417, 6418 and 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, powder and proteins, good alternative to those suffering from type I allergies.








## Recommendations for use:



### AQL 1.0

MEDICAL	2017/745 (EU)	CLASS I
PPE	2016/425 (EU)	CATEGORY III

REF	DESCRIPTION	SIZE CODE	OVERALL LENGTH	PACK COUNT dispenser/carton
6415	Examination gloves, Nitrile SVEA, blue/lilac, XS		240 mm	150/1500
6416	Examination gloves, Nitrile SVEA, blue/lilac, S		240 mm	150/1500
6417	Examination gloves, Nitrile SVEA, blue/lilac, M		240 mm	150/1500
6418	Examination gloves, Nitrile SVEA, blue/lilac, L		240 mm	150/1500
6419	Examination gloves, Nitrile SVEA, blue/lilac, XL		240 mm	150/1500

**Sales Unit:** Transport Carton

# Technical Summary

## Regulations

The product complies with legal requirements for medical devices and personal protective equipments.



<b>REACH regulation:</b>	The products covered by this data sheet does not contain any 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>Freedom of holes:</b> EN 455-1	AQL 1.0
<b>Force at break (N):</b> EN 455-2	≥ 6.0 before ageing ≥ 6.0 after ageing
<b>Biological evaluation:</b> EN 455-3	Total quantity of powder residues for powder-free glove < 2 mg/glove
<b>Compliance with legal requirements:</b>	Medical Device Regulation (EU) 2017/745, Class I Regulation (EU) 2016/425 on Personal Protective Equipment, Category III EC Declaration of Conformity for Personal Protective Equipment: <a href="http://www.onemed.com/what-we-do/doc-evercare">www.onemed.com/what-we-do/doc-evercare</a>
<b>Compliance with product standards:</b>	EN 455: 1 – 4
<b>Chemical resistance:</b>	Tested in accordance with EN 374-3 and/or EN 16523-1
<b>Food safety:</b>	The glove is suitable for all types of food handling – including fatty and acidic foods. Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.
<b>Other tests performed:</b>	Air leak and Water leak according to EN 374-2 (Level 2) Chemicals residue Cytotoxicity according to EN ISO 10993-5 Irritation and skin sensitization according to EN ISO 10993-10 Dexterity, length and pH according to EN 420 Mechanical performance according to EN 388 Microbiological quality RoHS compliance Resistance to degradation by chemicals according to EN 374-4 Viral penetration according to EN 374-5 and ASTM F1671
<b>Quality standards:</b>	EN ISO 13485
<b>Label information and packaging compliance:</b>	EN ISO 15223-1, EN 1041 and EN 420

## Material

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











## Warnings and Recommendations

<b>Warnings:</b>	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur. The product contains dithiocarbamates – not to be used in case of hypersensitivity to these substances.
<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> EN 455-4	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 mm
Transport Carton	Cellulose, TCF quality	385 x 250 x 250 mm
Packing Tape	Transparent, PVC-free	N/A

## Barcodes

REF	Single Pack	Dispenser	Transport Carton
6415	N/A	 6 438129 313109	 6 438129 513103
6416	N/A	 6 438129 313116	 6 438129 513110
6417	N/A	 6 438129 313123	 6 438129 513127
6418	N/A	 6 438129 313130	 6 438129 513134
6419	N/A	 6 438129 313147	 6 438129 513141