

SHORT DESCRIPTION

Disposable nitrile examination gloves. Non-sterile, ambidextrous, powder-free and latex-free.

INTENDED USE

For medical use and treatments under hygienic conditions. Personal protective equipment. Nitrile disposable protective gloves.

USAGE

These instructions for usage shall be used in combination with the nitrile gloves boxes guide. Each shipping box consists of 10 boxes, containing 100 pieces of disposable examination gloves each. Velvet Grip Gloves are classified as: a Personal Protective Equipment category III and Medical Devices Class I according to the European PPE Regulation (EU) 2016/425 and European Medical Device Regulation (EU) MDR 2017/745.

Velvet Grip disposable examination gloves meet the EN/ISO standards shown on their boxes. These particular nitrile gloves are made for a single use and shall therefore be disposed of accordingly after usage.

GENERAL INFORMATION + SIZES

Velvet Grip: blue gloves made of pure nitrile, min. 0.05 mm thickness, 1.5 AQL, made in China.

SIZES

0.120		
Sizes	Length in mm	Width in mm
S	240 mm	85 +/- 5 mm
М	240 mm	95 +/- 5 mm
L	240 mm	105 +/- 5 mm
XL	240 mm	114 +/- 5 mm



CAUTION FOR USAGE

Inspect the gloves carefully before usage for any kind of imperfection or wholes.

- DO NOT use damaged gloves
- Check proper glove size DO NOT gloves that are too small or too big.
- PLEASE note that damaged gloves CANNOT protect you from chemical risks
- For single use ONLY
- Remember to dispose of gloves accordingly with healthcare waste

INGREDIENTS / HAZARDOUS INGREDIENTS

Velvet Grip gloves may contain ingredients that cause irritation or allergic reactions. In case of any unwanted reaction, please seek medical advice immediately.

STORAGE / SHELF LIFE

Store accordingly gloves in a dry, clean and well-ventilated place to (Temperature 10-40°C). Avoid direct sunshine, heat, water, oxidising agents and ultraviolet lights. Store unused gloves in original boxes. 3 years shelf-life from the date of manufacture, if stored at a temperature of 25°C.

CLEANING

Gloves are designed for single use only – NO CLEANING possible

DISPOSAL

These gloves must be disposed of in compliance with MEDICAL/CHEMICAL regulations.

VERWENDUNG

- 1. In order to open the box, please use the marked part on the very upper side of the box.
- 2. Take out the required quantity of gloves and examine them for any damage.
- 3. Remove all jewelry from your hands and wrists.
- 4. Wash your hands thoroughly.
- 5. After putting the fingers into the cuffs, pull them up to the wrist.
- 6. Please check if fingers, palm and cuffs are properly attached.
- 7. Removal hold the cuffs and pull the gloves towards the fingers. Pull off the glove.



STANDARDS (including diagrams)



A notified body responsible for overseeing and auditing the manufacturer's facility and process. Conformity stated by adding to the CE mark a 4 digit number belonging to the responsible authority.



An authorized representative needed if the manufacturer is not located within Europe.



Familiarise yourself with the instruction before usage.



LOT number



Manufacturing date



Expiration date



REF - unique reference number







Defines requirements for protection against micro-organism risks





EN ISO374-4:2019 Degradation % -4.3% Defines requirements for protection against chemical risks such as degradation

ISO 13485:2016

For medical industry specific quality management systems

ISO 9001:2015

Defines the criteria for quality management systems

EN ISO 21420:2020

Defines requirements and testing methods for protective gloves

EN ISO 374-1:2016/Type C

Defines the requirements for protection against chemical risks (Type C – level 1)



Defines requirements for protection against chemical risks such as:

- Resistance to penetration
- Permeation
- Degradation



These gloves are non-sterile





For single use only. Once used the gloves need to be disposed of

Avoid moisture, store in a cool, dry space

Avoid direct solar and fluorescent light

Gloves should be stored at a temperature between 10 - 40°C



Acceptable Quality Level – is a defined acceptable measure level



EN 1186 is an European standard which defines whether a particular model of gloves is permitted and therefore safe for food contact.

EN455 1,2,3,4 EN 455 1-4 define requirements for:

- Freedom from holes.
- Physical properties such as dimensions and tensile strength.
- Biological evaluation (such as e.g. endotoxin contamination, powder residue etc.)
 The determination of the glove's shelf life

