INSTRUCTIONS FOR USE

Designation

Blue nitrile examination gloves, powder-free

General Characteristics

Material: Nitrile
Color: Blue
AQL: 0.25
Sterility: Non-sterile

Classification

1. Medical Device of class I, non-sterile, under (EU) Regulation 2017/745. Tested under the standards: EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009.
2. Personal Protective Equipment (PPE) of category III, under (EU) Regulation 2016/425. Tested under the standards:
   EN 420:2003+A1:2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-2:2019; EN ISO 374-4:2019; EN ISO 374-5:2016; EN 16523-1:2015+A1:2018; ISO 16604:2004.
   The notified body responsible for certification is BSI Netherlands Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, P.O. Box 74103, 1070 BC Amsterdam, The Netherlands. (2797).

Intended use

It is intended to be worn on the hands, usually in medical examination settings, to provide a barrier against potentially infectious materials, blood & body fluids, substances and saliva and other contaminants.

The primary purpose of examination gloves is to act as a protective barrier to prevent the possible transmission of diseases between healthcare professionals and patients during examination procedures. Gloves should be used solely according to their intended application.

Storage instructions

Do not expose to direct sunlight, ozone sources or sources of fire.
Store in a dry and cool place, at a temperature of 5-40°C.

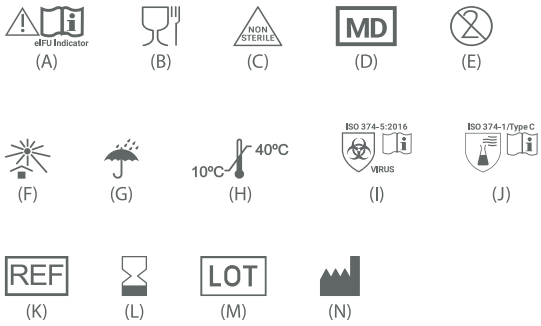
Chemical Protection

Chemical code letter	Chemical	Permeation level of protection	Degradation (%)
K	40% Sodium Hydroxide	6	-64,8

The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.
This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm where the cuff is tested also) and relates only to the chemical tested.
It can be different if the chemical is used in a mixture.

It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly.
For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
Before usage, inspect the gloves for any defect or imperfections.
Available sizes: **XS, S, M, L** and **XL.**

Symbols and Pictograms



CE 2797 Medical Device Class I, Non-sterile, under Regulation (EU) 2017/745
BSI Group The Netherlands B.V.Say Building, John M. Keynesplein 9,
1066 EP Amsterdam, P.O. Box 74103, 1070 BC Amsterdam The Netherlands
Personal Protective Equipment, Category III, under Regulation (EU) 2016/425

(O)

(A) Before using the product, consult the use instructions or contact Raclac, S.A. for more information; (B) Suitable for contact with foodstuffs; (C) Non-sterile; (D) Medical Device; (E) Single use; (F) Protect from direct sunlight; (G) Keep dry; (H) Maximum storage temperature 40°C and minimum temperature 10°C; (I) Protection against bacteria, fungi and viruses; (J) Protection against chemical risks: Type C = permeation break time > 10 minutes of protection against at least one test chemical from the list defined in EN ISO 374-1:2016 (no code indicated below the pictogram); (K) Reference (L) Shelf life; (M) Lot number; (N) Manufacturer; (O) The product complies with (EU) Regulation 2017/745 on class I medical devices and is compliant and has been certified in accordance with the requirements of (EU) Regulation 2016/425 on category III PPE. The CE marking is followed by the four-digit code referring to the identification number of the notified body responsible for the conformity assessment of category III PPE.

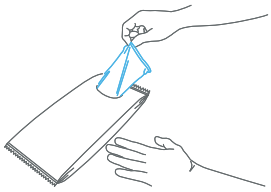
Shelf Life

3 years, after the production date.

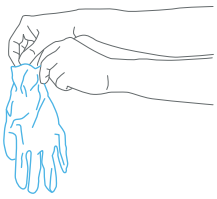
Manufacturer

RACLAC, S.A - Made in Portugal
Rua de Ribela 600, 4770-170 CRUZ, Portugal
+351 252 916 497 (national landline call)
www.raclac.pt

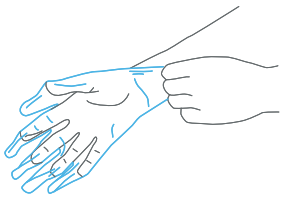
How to don gloves



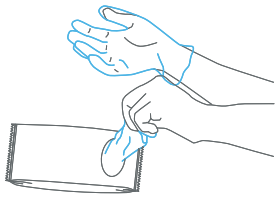
1. Take out a glove ***by the cuff*** *from its* ***flowpack.***



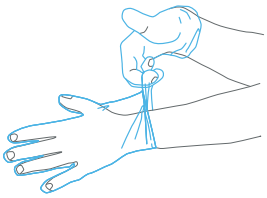
2. Touch only a ***restricted surface of the glove corresponding to the wrist*** *(at the top edge of the cuff).*



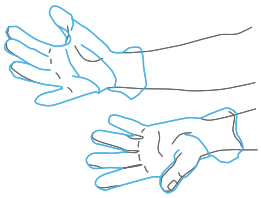
3. Don the first glove.



4. Take the second glove with the bare hand and ***touch only a restricted surface of glove corresponding to the wrist.***

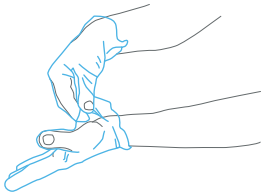


5. To avoid touching the skin of the forearm with the gloved hand, ***turn the external surface of the glove to be donned on the folded fingers of the gloved hand,*** *thus permiting to glove the second hand.*

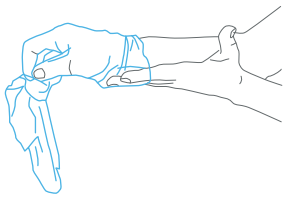


6. Once gloved, hands should not touch anything else *that is not defined by indications and conditions for the glove use.*

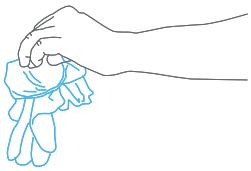
How to remove gloves



1. ***Pinch one glove at the wrist level to remove it,*** *without touching the skin of the forearm, and peel away from the hand, thus allowing the glove to turn inside out.*



2. Hold the removed glove in the gloved hand and ***slide the fingers of the ungloved hand inside between the glove and the wrist****. Remove the second glove by roling it down the hand and fold into the first glove.*



3. Discard the removed gloves.

Ensure flowpack is decontaminated between patients and follow local disinfection protocols.