INSTRUCTIONS FOR USE

R·green
For a better future!

Material: Nitrile

Color: Green

Sizes: XS | S | M | L | XL

AQL: 1.5

Sterility: Non sterile

Green nitrile examination gloves, powder-free

References: FP.RG1402.XS | FP.RG1402.S | FP.RG1402.M | FP.RG1402.L | FP.RG1402.XL

These instructions for use are intended to be used in combination with the specific information provided on the respective primary packaging.

DESCRIPTION

High comfort, dexterity, and resistance to puncture and tear. The fingertips are micro-textured, ensuring high tactile sensitivity. High elasticity providing excellent adaptability. Beaded cuff. Ambidextrous. Single use. Latex-free, with low allergy risk. Manufactured on a fully automated line (100%), with individual inspection of each unit.

CLASSIFICATION AND CE MARKING

Medical device of class I, non-sterile, in accordance with Regulation (EU) 2017/745. Personal protective equipment of category III, in accordance with Regulation (EU) 2016/425. Conformity assessment carried out by the notified body BSI Netherlands, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, P.O. Box 74103, 1070 BC Amsterdam, The Netherlands. (2797).

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

INTENDED USE

Intended for use by healthcare professionals in hospital environment, for the purpose of covering the hands and ensuring adequate protection of the patient against potential contamination.

STANDARDS

In compliance with the following standards: EN 455-1:2020+A1:2022; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2021; ISO 10993-11:2017;
ISO 10993-23:2021; EN ISO 21420:2020; 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.

ARKA
protecting life

MANUFACTURER:
ARKA, EUROPE, S.A.
Rua de Ribela 600, 4770-170 Cruz, Portugal
info@arkamedical.eu | Tel. +351 252 916 497
(call to a national landline)

Green nitrile examination gloves, powder-free

SYMBOLS AND PICTOGRAMS ON THE PACKAGING


(A)


(B)


(C)


(D)


(E)

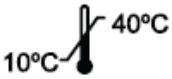
(F)

(G)

(H)


(I)


(J)



(K)


(L)

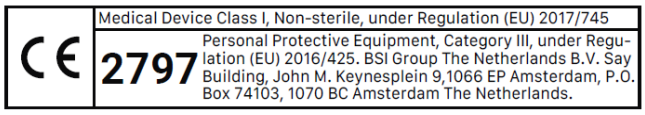
(M)

(N)

(O)

(P)

(Q)



(R)

(A) Before using the product, consult the instructions for use or contact ARKA, EUROPE, S.A. for further information. **(B)** Warning. **(C)** Manufacturer. **(D)** Date of manufacture. **(E)** Expiry date. **(F)** Batch number. **(G)** Reference. **(H)** Non-sterile. **(I)** Keep away from heat and radioactive sources. **(J)** Keep dry. **(K)** Storage temperature between 10°C and 40°C. **(L)** Single use. **(M)** Medical Device. **(N)** Unique Device Identifier. **(O)** Chemical risk protection - Type C = permeation breakthrough time > 10 minutes for protection against at least one chemical from the list defined in EN ISO 374-1:2016 (no code indicated below the pictogram). Tested substances: K = 40% Sodium hydroxide and T = 37% Formaldehyde. **(P)** Protection against bacteria, fungi and viruses. **(Q)** The product complies with UK MDR 2002. **(R)** The product complies with and is certified in accordance with the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment (PPE) category III. When the MD symbol accompanies the CE marking, the product is also classified as a Class I medical device according to Regulation (EU) 2017/745.

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INSTRUCTIONS FOR USE

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PRECAUTIONS FOR USE

1. Before use, carefully inspect the gloves for holes, tears, deformations, or any other visible defects. Do not use if damaged. **2.** The gloves are intended for single use only. Do not reuse. Reuse may compromise the protective barrier's effectiveness. **3.** The gloves offer limited protection against certain chemicals. Please consult the technical information provided by ARKA, EUROPE, S.A. before use with chemicals. **4.** Remove the gloves carefully, avoiding contact with the outer surface. Wash and disinfect hands after removal. **5.** Gloves must not be exposed to open flames or used as protection against heat or fire. **6.** The gloves are not suitable for protection against ionizing radiation, biological containment environments, or explosive atmospheres. **7.** Do not use if the packaging is damaged. **8**. The gloves are intended for temporary use, defined as continuous use of less than 60 minutes, in accordance with Regulation (EU) 2017/745. **9.** Gloves must be changed between procedures, when moving from a contaminated area to a clean area, after contact with bodily fluids, or when signs of damage or contamination are present, in order to maintain the barrier function and ensure the safety of both the user and the patient, preventing cross-contamination. **10.** In the event of a serious incident, it must be reported to ARKA, EUROPE, S.A. and to the Competent Authority of the Member State where the user and/or patient is located.

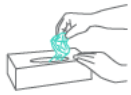
STORAGE AND TRANSPORTATION RECOMMENDATIONS

Keep in a dry place and protect from humidity, direct sunlight, fluorescent light, ozone, X-rays and excessive cold and heat. Dispose of in accordance with local regulations.

SHELF-LIFE

3 years after the manufacturing date.

GLOVES DISPENSING (WHO GUIDELINES)



1. Take out a glove from its original box.

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.

CHEMICAL PROTECTION

Letter chemical code	Name of the chemical	Permeation Level	Degradation (%)
K	40% Sodium hydroxide	6	2,9
T	37% Formaldehyde	4	44,5

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.

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