Nitrile Examination and Protective Gloves

The instruction below should be used in conjunction with detailed information on the packaging.

Product description

Non-sterile nitrile examination and protective gloves for single use. The gloves are ambidextrous, powder-free and latex-free. The textured outer surface guarantees a good grip and the beaded cuffs make it easier to put on the gloves and prevent the gloves from slipping.

Precautions and indications for use

Wash and dry your hands carefully before taking a glove from the packaging. Before usage, inspect the gloves for any defects. Put first your dominant hand into the glove and avoid touching the working surface. Then put the next glove on your other hand by using your dominant hand already wearing the glove. After both of the gloves are on your hands adjust the fit of the gloves. Ensure by streching that the gloves fit well against fingertips and your wrists are covered.

When taking the gloves off, start by holding on the cuff of the glove on your dominant hand with a finger of the other hand. Pull the glove carefully off inside out without touching the external surface of the glove. Then pull the other glove carefully off inside out in the same way by only touching the internal surface of the glove.

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 case where 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 the 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.

Material

Nitrile

External surface

Textured

Internal surface

Polymerized / Chlorinated

Colour

Blue

Package size

100 pcs by weight

Shelf life

5 years

AQL

1.5

Intended use / Application

Intended to be used in healthcare, laboratory, cleaning, food and beauty industries to protect the user and others (e.g. patient) from cross-contamination.

Storage instructions

Store at the recommended storage temperature 5-35°C in a dry place away from sunlight and fluorescent light. Recommended relative humidity in the storage is 60 ±20%. Store the gloves in a distance of at least 1 meter from heating devices, sources of fire and ozone. Do not store the gloves in direct vicinity of solvents, oils, fuels and lubricants.

Disposal

Used gloves can be contaminated with contagious or other hazardous substances and should be disposed according to local regulation.

Components / Hazardous components

The gloves may contain components which can possible cause irritation or allergic reactions. In case of an allergic reaction, contact healthcare professionals immediately.

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MDR classification and compliance

Class I according to Annex VIII of the Regulation (EU) 2017/745.
The gloves are complient with the following standards:
EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015,
EN 455-4:2009, EN ISO 15223-1:2021, EN ISO 21417:2019.

PPE classification and compliance

Category III Personal Protective Equipment as per Annex I of the Regulation 2016/425. The gloves are complient with the following standards: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016.

Declaration of conformity and instructions for use are available at https://www.bernermedical.fi/tuote/bea-pro-nitriilikasine-sku-bpng100/

Manufacturer

Berner Ltd
Hitsaajankatu 24, 00810 Helsinki Finland
www.bernermedical.fi

Notified Body 2777 responsible for EU Type Examination (Module B) and Module C2 On-going Conformity:
Satra Technology Europe Ltd
Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland

CE 2777

Bea Pro Nitrile glove XS
Product number: BPNG1001
Sales batch: 10 boxes
Pallet: 600 boxes
GTIN Consumer package: 6414505172980
GTIN Transport package: 6414505172997

Bea Pro Nitrile glove S
Product number: BPNG1002
Sales batch: 10 boxes
Pallet: 600 boxes
GTIN Consumer package: 6414505173000
GTIN Transport package: 6414505173017

Bea Pro Nitrile glove M
Product number: BPNG1003
Sales batch: 10 boxes
Pallet: 600 boxes
GTIN Consumer package: 6414505173024
GTIN Transport package: 6414505173031

Bea Pro Nitrile glove L
Product number: BPNG1004
Sales batch: 10 boxes
Pallet: 600 boxes
GTIN Consumer package: 6414505173048
GTIN Transport package: 6414505173055

Bea Pro Nitrile glove XL
Product number: BPNG1005
Sales batch: 10 boxes
Pallet: 600 boxes
GTIN Consumer package: 6414505173062
GTIN Transport package: 6414505173079

ISO 374-5:2016
VIRUS

Test acc. to EN ISO 374-5:2016

Protection against bacteria & fungi	PASS
Protection against viruses	PASS

Test acc. to EN ISO 374-2:2019 – Level 2 (ISO 2859)
Performance level: Level 3 - AQL < 0.65
Level 2 - AQL < 1.5
Level 1 - AQL < 4.0

ISO 374-1/TYPE B
KPT

Test acc. to EN ISO 374-1:2016+A1:2018 (Type B)	Level	Test acc. to EN ISO 374-4:2019 Degradation %
10% Acetic Acid	4	53.5
50% Benzalkonium Chloride*	6	29.0
4% Chlorhexidine Digluconate**	6	32.9
10% Phosphoric Acid	6	14.0
40% Sodium Hydroxide (K)	6	2.6
12% Sodium Hypochlorite	6	22.7
50% Sulphuric Acid	6	21.1
5% Ethidium Bromide	6	32.9
3% Hydrogen Peroxide	6	44.0
30% Hydrogen Peroxide (P)	2	52.8
37% Formaldehyde (T)	5	20.0
50% Glutaraldehyde	6	22.9
0.1% Phenol	6	24.7

*minimum detectable permeation rate: 5 µg/cm2/min
**minimum detectable permeation rate: 7 µg/cm2/min

Permeation performance levels as per
EN ISO 374-1:2016+A1:2018
Level 1 > 10 min
Level 2 > 30 min
Level 3 > 60 min
Level 4 > 120 min
Level 5 > 240 min
Level 6 > 480 min

EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

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Test acc. ASTM D6978-05

Test Chemotherapy Drugs	Minimum breakthrough detection time (Specimen 1/2/3) [minutes]
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	24.6 (24.6, 27.7, 26.9)
Cisplatin 1.0 mg/ml (1,000 ppm)	240
Cyclophosphamide (Cytoxan) 20.0 mg/ml (20,000 ppm)	240
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	240
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	240
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	240
Flouorouracil 50.0 mg/ml (50,000 ppm)	240
Methotrexate 25 mg/ml (25,000 ppm)	240
Mitomycin C 0.5 mg/ml (500 ppm)	240
Paklitaksel (Taxol) 6.0 mg/ml (6,000 ppm)	240
Thiotepa (THT) 10.0 mg/ml (10,000 ppm)	68.9 (76.6, 97.6, 68.9)
Vincristine 1.0 mg/ml (1,000 ppm)	240

Food contact

Gloves are marked with food contact symbol and comply with the requirements of Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Gloves are suitable for handling any type of food and have been tested for Overall Migration Test acc. EN 1186.

For more detailed information please contact the manufacturer.

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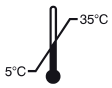
SYMBOLS USED ON THE PACKAGING

	Medical device		Suitable for food contact (for details check the instruction for use)
	Personal Protective Equipment		Package made from paper, qualify for recycling
	Latex-Free		Consult instructions for use
	For single use only		LOT number
	Non-sterile		Expiry date
	Do not use if package is damaged		Country of manufacture accompanied by date of manufacture
	Keep away from sunlight		Manufacturer
	Keep dry (protect from moisture)		Article number
	Store at the temperature 5-35°C		Package is treated as municipal waste
	Protection against chemicals - Marking of Type B chemical resistant glove	 ASTM D6978-05	Protection against chemotherapy drugs acc. to ASTM D6978-05
	Protection against micro-organism hazard (viruses, bacteria, fungi) - acc. to EN 374-5		

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