MEDECO BV
A MEDIQ COMPANY

User Information

Product Reference : Klinion® Personal Protection powder-free nitrile gloves

Available sizes : XS, S, M, L, XL

Manufacturer Address : Medeco BV
Alexander Flemingstraat 2
3261 MA Oud-Beijerland
Netherlands

1. EU Type-Examination

1.1. This product is classed as Category III Personal Protective equipment according to European PPE Regulation 2016/425 and has been shown to comply with this Regulation through the Harmonised European Standards EN 420:2003+A1:2009, EN ISO 374-1:2016, and EN ISO 374-5:2016

1.2. Notified Body responsible for certification and Module B compliance is SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Republic of Ireland NB number 2777.

1.3. Notify Body responsible internal production control plus supervised product checks at random intervals (Module C2) is SATRA Technology Europe Limited, Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Republic of Ireland NB number 2777.

1.4. EU Declaration of Conformity is accessible at www.medeco.org

Tested in accordance with EN ISO 374-5:2016 Virus	The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.		
Tested in accordance with EN ISO 374-1:2016/Type B KPT		EN16523-1:2015 Permeation Level	EN374-4:2013 Degradation
	K = 40% Sodium Hydroxide	6	-42.9%
	P = 30% Hydrogen Peroxide	2	22.8%
	T = 37% Formaldehyde	3	5.0%

ISO374-1:2016 Permeation levels are based on breakthrough times as follows:

Performance level	1	2	3	4	5	6
Minimum breakthrough times (mins)	10	30	60	120	240	480

EN374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical

2. Performance and Limitation of Use

a. This product has been tested in accordance with EN ISO 374-1:2016, EN 374-4:2014 and EN ISO 374-5: 2016 and achieved the following levels:

EN ISO 374-1: 2016 (Type C)	EN16523-1:201 Permeation performance Level	EN 374-4:2013 Degradation %
4% Chlorhexidine Digluconate*	6	19.0
40% Sodium Hydroxide (K)	6	-42.9
10-13% Sodium Hypochlorite	6	14.7
50% Sulphuric Acid	6	-20.5
10% Acetic Acid	4	66.7
5% Ethidium Bromide	6	3.4
37% Formaldehyde (T)	3	5.0
50% Glutaraldehyde	6	27.4
0.1% Phenol	6	33.8
30% Hydrogen Peroxide (P)	2	22.8
1.5% Methanol in Water	6	21.9
25% Ammonium Hydroxide (O)	1	-52.0
3% Povidione-iodine	6	33.7
10% Sodium Percarbonate	6	15.4
20% Benzalkonium Chloride**	6	4.9
25% Hydrochloric Acid	6	-2.1
5% Methanol	6	23.8
30% Phosporic Acid	6	18.3
30% Potassium Hydroxide	6	33.4

* Permeation rate 7 µg/cm^2/min

** Permeation rate 33 µg/cm^2/min

EN ISO 374-5:2016 :

Protection against Bacteria & Fungi: Pass

Protection against viruses Pass

b. 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.

c. This product provides protection against bacteria, fungi and virus. The gloves had been tested in accordance with ISO 16604:2014 to meet the requirements of EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage.
    i. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

d. The gloves were found to meet with the REACH annex XVII requirements for Polycyclic Aromatic Hydrocarbons (PAHs).

e. Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek for medical advice immediately.

3. Gloves for Special Applications (EN 420:2003+A1:2009, Clause 5.1.3)

The Klinion® Personal Protection examination gloves are intended to be worn on the hand for medical purposes and to help prevent contamination between patient and examiner. Therefore, the length of the gloves is below EN requirements of total minimum glove length, and deems as 'Fit for Special Purpose'.

4. Instruction for Use

4.1. Usage – For Single Use only. If re-used, the risk of contamination and infection increases due to improper cleaning processes; and increased risk of holes and tear during re-use due to weakening of gloves by cleaning processes.

4.2. Sizing – Select the right size glove for your hand.

4.3. Donning – Hold glove by the bead with one hand. Align the glove thumb with your other hand thumb and slide your hand into the glove, one finger into each glove finger. Pull by the glove palm to a get a good fit. Don the other glove by the same procedure.

4.4. Inspection – Punctures or tears may occur after donning. Inspect each glove after donning, and immediately discontinue use if found damaged.

4.5. Doffing – Hold glove bead and pull toward the finger until the glove come off.

4.6. Disposal – Properly disposal of all used gloves. Follow your Institution's policies for disposal.

5. Handling and Storage

Store in a cool and dry place. Opened boxes should be kept away from fluorescent and sunlight. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

6. Shelf life

The shelf life of product is 3 years from date of manufacture.