

Powder Free Nitrile Examination Gloves



USER INFORMATION

CE 2777

This product complies as Class 1 medical device under Medical Device Regulation (EU) 2017/745 and PPE Regulation (EU) 2016/425 CAT III for special purpose. Tested in accordance to EN 455 : 1,2,3,4

Product reference:

XS (5/6) - C1900-24
S (6/7) - C1901-24
M (7/8) - C1902-24
L (8/9) - C1903-24
XL (9/10) - C1904-24

Glove sizes available: XS, S, M, L and XL



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Notified Body responsible for EU Type Examination and Module C2 ongoing conformity:
SATRA Technology Europe Ltd,
Bracetown Business Park, Clonee,
Dublin 15, Dublin Ireland.
(Notified Body Number: 2777)



Storage and transport: When not in use, store the product in a well-ventilated area away from extremes of temperature. Check for damage before use, do not use damaged gloves.

Performance and limitation of use: This product has been tested in accordance with EN ISO 374-1:2016 + A1:2018, EN ISO 374-5:2016 and achieved the following performance levels:

EN ISO 374-5:2016 Protection against bacterial and fungi Pass
Protection against viruses Pass

<p>Tested in accordance with ISO 374-5:2016</p>  <p>VIRUS</p>	<p>Tested against viruses The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.</p>
<p>Tested in accordance with ISO 374-1/Type B</p>  <p>KPT</p>	<p>Tested in accordance with EN ISO 374-1:2016 + A1:2018</p>

EN ISO 374-1:2016 + A1:2018 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

Chemical	Level	Mean 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
3% Povidone - iodine	6	33.7
10% Sodium Percarbonate	6	15.4

*The minimum observable permeation rate was 7µg/cm²/min.

EN ISO 21420:2020 and ISO 21420:2020/Amd.1:2022

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

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 400mm – 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.

Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek for medical advice immediately. Recommend to store at room temperature prevailing in respective countries.

This glove does not protect against mechanical risks and ionizing radiation.

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 get a good fit. Don the other glove by the same procedure.

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

Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

Where relevant, a list of the substances contained in the glove which are known to cause allergies, per listed in Annex G of EN ISO 21420:2020, shall be supplied on request.

EU Declaration of Conformity is accessible at www.fannin.eu.