Product code	9655
Product Name	POWDER FREE NITRILE EXAMINATION GLOVE, BLUE, WHITE, BLACK COLORED, NON-STERILE
Available size	XS, S, M, L, XL, XXL, XXXL
Manufacturer	Excia Resources Sdn Bhd F-3-6, Pacific Place, Jalan PJU 1A/4A, Ara Damansara, 47301 Petaling Jaya, Selangor D.E., Malaysia.

1) Personal Protective Equipment (PPE) Regulation (CE certification)

a) This product is classified as **Category III** Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425 and has been shown to comply with this Regulation through the Harmonised European Standards EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374- 5:2016 and and EN 421:2010.

b) Notified Body responsible for certification and Module B compliance is SATRA Technology Europe Limited (2777), Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland.

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

d) EU Declaration of Conformity is accessible at **www.excia.asia**

2) Indication For Use (IFU)

A Powder Free Nitrile Examination Gloves is a disposable glove made of nitrile rubber that is intended to wear on the hand for medical purposes to provide a barrier against potentially infections materials and other contaminants. In addition, this product demonstrated reduced potential risk for sensitizing users to chemical additives.

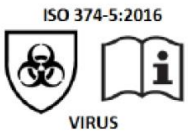
These gloves are also intended to protect against risks associated with contact against certain chemicals, microorganisms and radioactive contamination, where hand protection is of priority.

3) Usage

For single use only. If re-used:
i. Extremely high risk of cross-contamination
ii. Deterioration of barrier protection
iii. Deterioration of glove properties
iv. Lost of lot traceability

4) Marking

a) **Microorganism Hazards Pictogram:** EN ISO 374-5:2016 Protect against Bacteria, Fungi and Virus. No penetration of bacteriophage through the specimen and the following pictogram is applied.



b) **Chemical Hazards Pictogram:** BS EN 16523-1:2015+A1:2018; Additional information on chemical resistance obtainable from manufacturer.

EN ISO 374-1:2016+A1:2018 permeation levels are based on breakthrough times as follows:

Permeation Performance Level	1	2	3	4	5	6
Measured breakthrough time (min)	>10	>30	>60	>120	>240	>480

This product complies with Type B requirements and the following pictogram shall be used with reference to clause 6.2 of EN ISO 374-1:2016+A1:2018.

c) Radioactive Contamination Pictogram: EN 421:2010 Protect against particulate radioactive contamination. Protect against contact with radioactive contaminants, but not against ionizing radiation.

5) Performance and Limitation of Use

a) This product was tested in accordance to test method specified under EN ISO 374-2:2019 and ISO 16604:2004, complying with EN ISO 374- 5:2016.
Protection against bacteria and fungi - Pass
Protection against viruses - Pass

b) These gloves were tested in accordance with BS EN 16523-1:2015+A1:2018 resistance to permeation by chemicals and achieved the following performance levels:-

Chemicals	**Performance Level**
40% Sodium Hydroxide (K)	6
10-13% Sodium Hypochlorite	6
50% Sulphuric Acid	6
5% Ethidium Bromide	6
37% Formaldehyde (T)	4
50% Glutaraldehyde	6
0.1% Phenol	6
n-Heptane (J)	3
1.5% Methanol in water	6
30% Hydrogen Peroxide (P)	2

i) This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

ii) 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 used in a mixture.

iii) 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.

iv) 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.

c) This product was tested in accordance with EN ISO 374-4:2019 and achieved the following degradation results:-

Chemicals	**Mean Degradation / %**
40% Sodium Hydroxide (K)	2.8
10-13% Sodium Hypochlorite	23.9
50% Sulphuric Acid	-50.8
5% Ethidium Bromide	-12.0
37% Formaldehyde (T)	59.4
50% Glutaraldehyde	4.5
0.1% Phenol	9.4
n-Heptane (J)	47.2
1.5% Methanol in water	-12.3
30% Hydrogen Peroxide (P)	18.8

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

d) This product provides protection against bacteria, fungi and virus. The gloves were tested in accordance with ISO 16604:2004 to meet EN ISO 374-5:2016 requirements of penetration resistance of blood-borne pathogens, Phi-X174 bacteriophage.

The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

e) This product meets the REACH annex XVII requirements of Polycyclic Aromatic Hydrocarbons (PAHs).

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

6) Contraindications
Persons who are known to be sensitized with chemical additives should avoid contact with this glove.

7) Warnings
Do not use if the glove is visibly torn, frayed or damaged.

8) Storage conditions
Store in a cool and dry place. Recommend to store at room temperature prevailing in respective countries. 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.

9) Instruction for Use
a) Before usage, inspect the gloves for any defect or imperfections.

b) 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.

c) Sizing – Select the right size glove for your hand.

d) 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.

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

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

g) Disposal – Properly dispose of all used gloves. Follow the local regulations and your institution's policies for proper disposal.

10) Shelf life
The shelf life of product is 5 years from date of manufacture.

11) Reporting
In the event of any serious incident occurring in relation to the use of this device, please report to the manufacturer or its authorised representative, and the competent authority of the Member State in which the user is established.