User Information Sheet

Ultra***SAFE*** Violet Nitrile Gloves

	Product name	UltraSAFE Violet Nitrile Gloves
	Product codes	1116, 1117, 1118, 1119
	Available sizes	Small, Medium, Large, Extra large
	Manufacturer	PRO Hygiene Products, PO Box 168, BRISTOL, BS31 9EE, UK

1) PPE EU Type-Examination

This product is classified as Category I 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.

a) The EU Declaration of Conformity is accessible at www.prohygieneproducts.com.

2) Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) – UKCA mark

a) In compliance with Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK MDR 2002).

b) This product is classified under **Class I** Medical Device per Rule 1 and Rule 5 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.

c) This product complies with Designated Standards BS EN 455-1:2020, BS EN 455-2:2015, BS EN 455-3:2015, and BS EN 455-4:2009.

3) Personal Protective Equipment (PPE) Regulation (UKCA Certification)

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

b) UK Approved Body responsible for certification and Module B compliance is BSI Assurance UK Ltd (AB0086), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK.

c) UK Approved Body responsible for quality assurance of the production process (Module D) is BSI Assurance UK Ltd (AB0086), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

d) The UK Declaration of Conformity is accessible at www.prohygieneproducts.com

4) **Indication For Use (IFU)**

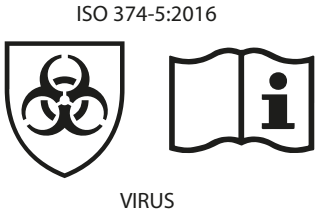
A Powder Free Nitrile Examination Gloves is a disposable glove made of nitrile rubber that intended to wear on the hand for medical purposes to provide a barrier against potentially infections materials and other contaminants. These gloves are also intended to protect against risks associated with contact against certain chemicals, chemotherapy drugs, and microorganisms, where hand protection is of priority.

5) 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) Loss of lot traceability

6) Marking

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



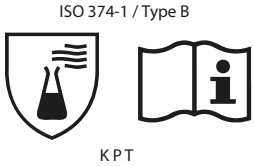
b) **Chemical Hazards Pictogram**: BS EN 16523-1:2015+A1:2018; Additional information on chemical resistance obtainable from manufacturer.

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

Permeation Performance level	**0**	**1**	**2**	**3**	**4**	**5**	**6**
Measured breakthrough time (min)	*	>10	>30	>60	>120	>240	>480

* Indicates that the glove falls below the minimum performance level as stated in BS EN ISO 374-1:2016+A1:2018 for the given individual hazard.

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



7) Performance and Limitation of Use

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

i) Protection against bacteria and fungi – Pass

ii) 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 BS EN ISO 374-4:2019 (degradation), and achieved the following performance levels and mean degradation:

Chemicals	**Performance Level**	**Mean Degradation / %**
Toluene (F)	0	62.2
n-Heptane (J)	1	18.7
40% Sodium Hydroxide (K)	6	-66.1
96% Sulphuric acid (L)	0	100.0
25% Ammonium Hydroxide (O)	1	31.6
30% Hydrogen Peroxide (P)	5	26.9
37% Formaldehyde (T)	6	-9.0
5% Ethidium Bromide	6	-33.8
50% Glutaraldehyde	6	-42.5
70% Isopropanol	2	25.9
0.1% Phenol	6	-3.7
1.5% Methanol	6	-20.3

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.

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

c) This product provides protection against Bacteria, Fungi and Virus. The gloves had been tested in accordance with ISO 16604:2004 to meet the requirements of BS EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage. 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.

8) Contraindications

Persons who are known to be sensitized to chemical accelerators should avoid contact with this glove.

9) Warnings

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

10) Storage conditions

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.

11) 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 disposal of all used gloves. Follow your Institution's policies for disposal.

12) Shelf life

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

13) Reporting

In the event of any serious incident occurred 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.

14) Additional Information

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.

PRO Hygiene Products PO Box 168, BRISTOL, BS31 9EE, UK www.prohygieneproducts.com