















REF **N1191M/N1192L**

 LATEX FREE	Latex Free. Refer to the label of each glove.	 10 °C 40 °C	It should be stored between 10 °C and 40 °C
	Keep out of direct sunlight. Store in a dry place.	 AQL 1.5	AQL is 1.5
	Do not use if box is damaged.		Expiry Date
	Country of origin		Legal manufacturer
	Non-sterile medical device		Single use only
 RECYCLABLE BOX	The box is recyclable	 PAPER ONLY	The IFU is recyclable
	Consult the IFU for important cautionary information.		Date of manufacture

EU-TYPE ASSESSMENT CONDUCTED BY:

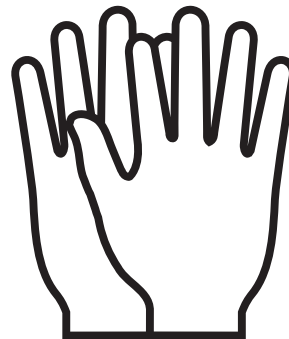
SATRA Technology Europe LTD
 Bracetown Business Park, Clonee, Co.
 Meath D15YN2P – Ireland

SATRA Technology Europe is also responsible for the continuous compliance of its products.



Distributed by:
Optimum Medical Solutions Ltd
 Tennant Hall, Blenheim Grove,
 Leeds, LS2 9ET, United Kingdom
 T: +44(0) 845 643 5479
 enquiries@optimummedical.co.uk
 www.optimummedical.co.uk

optipro.TM
 nitrile gloves



OptiProNitrileGloves-IFU-JUL24-V1.0

INSTRUCTIONS FOR USE

OptiPro Nitrile Gloves

PRODUCT REF / CONTENTS

Product Code / Description

OM Reference	Manufacturer Reference	Description
N1191M	ZHPFN02M	Nitrile Gloves – Medium
N1192L	ZHPFN02L	Nitrile Gloves – Large

This is a product information leaflet for the user.

Read all of the product information leaflet prior to use and retain for your information.

PRODUCT DESCRIPTION

OptiPro Nitrile Gloves are sterile, single-use nitrile gloves designed to protect the hands against micro-organisms (bacteria, moulds, viruses) and chemical hazards.

INDICATIONS FOR USE / INTENDED USER

OptiPro Nitrile Gloves are indicated for protection of the user and the patient during use.

Technical characteristics:

- Class I medical device, Category III PPE.
- Single-use, non-sterile device.
- Gloves are used on healthy skin.

CONTRAINDICATIONS

Do not use the **OptiPro Nitrile Gloves** if you are sensitive or allergic to any of the device ingredients.

PRECAUTIONS

- Do not open the box with a sharp object.
- Before use, check the integrity of the glove (perforation, tear). If gloves tear or puncture during use, discard them. If in doubt, do not use them and take a new pair.
- Do not use **OptiPro Nitrile Gloves** if they are damaged or soiled.
- This glove does not protect against mechanical hazards or ionising radiation. Do not wear these gloves in a containment enclosure.
- Avoid exposing gloves to an open flame.
- The combined use of this device with other higher-class PPE cannot extend the scope of the device. The user is solely responsible for choosing the right combination and adaptation of the glove with other equipment as well as the period during which the glove can be worn, depending on the task to be

performed, the level of protection required and the comfort of use.

- Not all food contact gloves are suitable for all foods. With certain types of foods, some gloves may demonstrate excessive migration.
- This is a single-use device. Re-use of this device may result in patient infection / cross-contamination.
- **OptiPro Nitrile Gloves** are Latex Free.

WARNING:

Chemical resistance data is obtained from assessments carried out under laboratory conditions on palm samples only (except in cases where the glove is equal to or greater than 400 mm - where the cuff is also tested), and refer exclusively to the tested chemical substances. Results may vary due to chemical mixtures. EN 374-4: 2019 The degradation test results indicate the alteration of the puncture resistance properties of the gloves after exposure to the test chemical. This information does not reflect the actual duration of use in the workplace and does not differentiate between pure chemicals and mixtures.

Penetration resistance was assessed under laboratory conditions and only applies to the sample tested. Make sure the gloves are suitable for the intended use. Workplace conditions (temperature, abrasion and degradation) may differ from the typical test. During use, gloves are likely to provide less resistance to the chemical substance due to a change in their physical properties. Movements, snags, friction and degradation caused by exposure to the chemical can significantly reduce the actual duration of use. If corrosive chemicals are used, degradation becomes the primary factor in the choice of chemical resistant gloves. Permeation data of chemicals according to EN ISO 374-1: 2016+A1: 2018 and degradation data according to EN 374-4: 2019 are available on the package.

UNDESIRABLE SIDE EFFECTS

In rare cases, local irritation/hypersensitivity reactions may occur such as redness, itching or blistering. If this occurs, stop using **OptiPro Nitrile Gloves** and consult a Healthcare Professional.

Any serious incident or malfunction that has occurred in relation to the **OptiPro Nitrile Gloves** should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

HOW TO USE

Wash hands before and after wearing the gloves; ensure hands are dried properly.

Choose the appropriate size. The gloves are ambidextrous: they can be worn on both hands. Insert five fingers into the cuff and pull the cuff on the wrist as far as possible. Make sure the glove fits snugly around the fingers and palm. Pull the glove(s) on fully. The cuff should be snug around the wrist. To achieve the desired protection, this glove

can be used with other PPE or protective medical devices (coveralls, gowns, footwear, respiratory protection equipment, etc.).

Special precautions for dressing and undressing may depend on the field of application (e.g. double gloving).

To remove the gloves, grasp the outside of the glove near the wrist; remove the glove from the hand by turning it inside out.

Hold it in the opposite gloved hand. Slide a non-gloved finger under the wrist of the remaining glove, taking care not to touch the outside of the glove. Peel off the remaining glove from the inside to create a "bag" containing both gloves. Dispose of them properly.

Do not use if packaging is damaged or unintentionally opened prior to use.

STORAGE AND HANDLING

Store between 10-40°C (50-104°F) until expiry date.

Keep the gloves in their original packaging, away from humidity, sunlight and light. Keep dry.

Unopened packs have a 5-year shelf life.

Do not use after expiry date.

DISPOSAL

Depending on the field of application, the user must comply with the national regulations in force for the device and its packaging.

Gloves are for single use only and are not designed to be washed or reused. They must be disposed of after use.

MANUFACTURER INFORMATION





































Zhonghong Pulin Medical Products Co., Ltd.,
West Industrial Park, Luannan County Tangshan City,
Hebei, China, 063500.
www.zhonghongpulin.com

DISTRIBUTED BY

Optimum Medical Solutions Ltd, Tennant Hall, Blenheim Grove, Leeds, LS2 9ET, UK.
Tel: +44 (0) 845 643 5479
Email: enquiries@optimummedical.co.uk
Website: www.optimummedical.co.uk

UK REPRESENTATIVE

MedPath Limited, 27 Old Gloucester Street, London, WC1N 3AX, England,
United Kingdom

	- Class I medical device (MD), in accordance with European regulation. EU 2017/745	
	- Category III personal protective equipment (PPE), in accordance with European regulation (EU) 2016/425. The conformity assessment was carried out by the notified body SATRA Europe (No 2777)	
	The device is in conformity with the applicable requirements for products sold within Great Britain.	
	The device is in conformity with personal protective equipment (PPE) Regulation (EU) 2016/425 as amended and brought into UK law.	
	EN ISO 21420: Protective gloves - general requirements and test methods. Read the instructions before use	
EN ISO 374-1/type A  UVWXYZ	EN ISO 374-1: 2016+A1: 2018/ Type A, B or C: Protective gloves against dangerous chemicals and micro-organisms.	
EN ISO 374-1/type B  XYZ	Type A: more than 30 minutes for at least six test chemicals present in the standard. "UVWXYZ" represent the codes for test chemicals.	
EN ISO 374-1/type C  UVWXYZ	Type B: more than 30 minutes at least for three test chemicals present in the standard. "XYZ" represent the codes for test chemicals.	
EN ISO 374-1/type C  UVWXYZ	Type C: more than 10 minutes for at least one test chemical present in the standard.	
EN ISO 374-5: 2016  VIRUS	EN ISO 374-5: 2016/ VIRUS Protection against bacteria, fungi and viruses.	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	
	Lot Number	

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

Suitable for food contact.
Certified according to European regulations 1935/2004 and 10/2011. Refer to the label of each glove