

## INSTRUCTION FOR USE

### NAME AND ADDRESS OF THE MANUFACTURER.

#### Manufacturer:

Maxter Glove Manufacturing Sdn Bhd

Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia.

### PRODUCT DESCRIPTION

Non Sterile Powder Free Nitrile Examination Gloves are made from 100% synthetic rubber, ambidextrous, coloured and for single use. It is treated with chlorine which is to facilitate the user in donning the glove. Gloves have high strength and flexibility, while at the same time they are soft and well retain the original shape. Gloves are ambidextrous with a comfortable rim and extended cuff that ensures easy donning, ideal fit, secure fixing (the glove does not slip) and the rapid removal of gloves at the end of the manipulation.

These gloves are to protect user's hands against microorganism (bacteria, fungus and viruses) and certain chemical risks. Testing and marking on the gloves are in accordance with Regulation (EU) 2016/425 as well as applicable harmonized European Standards. The gloves are to be used strictly for the intended applications. Potential consumers of these gloves may be personnel from medical and preventive institutions, private clinics, dentist, nurses, cosmetologist, lab personnel, food industry personnel and forensic personnel.

#### Declaration of Conformity

A copy of the declaration of conformity can be requested through email below:

[info@maxter.com.my](mailto:info@maxter.com.my)

### PERFORMANCE LEVELS AGAINST CHEMICAL AND MICRO-ORGANISMS HAZARDS

As per EU type examination issued by SATRA Technology Europe Ltd (Notified Body No.: 2777) located at Bracetown Business Park, Clonee, County Meath, Dublin 15, Ireland.

#### **7.0 mil (8.2g – 8.6g) Powder Free Nitrile Examination Gloves**

**Product reference : PFHN-GTO and PFHN-GTBK**

Article No.	Brand Name	Size*	Remarks
97885, 97895	Maxter	X-SMALL Hand Size (6)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
97886, 97896	Maxter	SMALL Hand Size (7)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
97887, 97897	Maxter	MEDIUM Hand Size (8)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
97888, 97898	Maxter	LARGE Hand Size (9)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
97889, 97899	Maxter	X-LARGE Hand Size (10)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.

EN420:2003+A1:2009

\* Hand circumference and length

Hand Size	Hand Circumference (mm)	Hand Length (mm)
6	152	160
7	178	171
8	203	182
9	229	192
10	254	204

Glove Size	Fits	Minimum Length (mm)
6	Hand size 6	220
7	Hand size 7	230
8	Hand size 8	240
9	Hand size 9	250
10	Hand size 10	260

**EN ISO 374-1:2016/Type B**



**JKPT**

The permeation performance of the gloves against chemicals

Level 2 – n-Heptane (J)

Level 6 – Sodium Hydroxide 40% (K)

Level 4 – Hydrogen Peroxide 30% (P)

Level 6 – Formaldehyde 37% (T)

The protection performance of the gloves against bacteria, fungi and viruses

Protection against bacteria and fungi –Pass

Protection against viruses- Pass

**EN ISO 374-5:2016**



**VIRUS**

**NOTIFIED BODY OF THE ONGOING CONFORMITY ASSESSMENT BASED ON  
REGULATION (EU) 2016/425, ANNEX VIII (MODULE D)**



For gloves against chemical and microorganism hazards, conformity to Regulation (EU) 2016/425 Annex VIII (Module D) is under the supervision of SGS FIMKO OY (0598), located at Takomotie 8, FI-00380 Helsinki, Finland.

## **STORAGE CONDITIONS**

Do not store Non Sterile Powder Free Nitrile Examination Gloves where temperature may rise above 104°F (40°C). Store in cool, dry and well ventilated area. Opened boxes of Non Sterile Powder Free Nitrile Examination Gloves should be shielded from exposure to direct sunlight or fluorescent lighting. Improper storage of Non Sterile Powder Free Nitrile Examination Gloves will result in decreased shelf life and compromised efficiency.

## **USE**

These gloves are designed to protect user's hands against microorganism and certain chemical risks. Testing and marking on the gloves are in accordance with Regulation (EU) 2016/425 as well as applicable harmonized European Standards. Please ensure the gloves are used strictly for the intended applications.

## **CAUTION**

Primary material – Nitrile rubber. Does not contain natural rubber latex. Components used in making gloves may cause allergic reactions in some users.

## **WARNING**

EN374-4:2013 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.

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

## **CLEANING**

Not applicable, as the glove is single use in intended manner.

**COMPREHENSION ON PERFORMANCE LEVEL**

<b>Method</b>	<b>Description</b>	<b>Requirements</b>	<b>Result</b>
<b>EN 16523-1</b>	Permeation 37% Formaldehyde	different classes 1: >10min 2: >30min 3: >60min 4: >120min 5: >240min 6: >480min	> 480 minutes
<b>EN 16523-1</b>	Permeation n-Heptane	different classes 1: >10min 2: >30min 3: >60min 4: >120min 5: >240min 6: >480min	Minimum 57 minutes
<b>EN 16523-1</b>	Permeation 40% Sodium Hydroxide	different classes 1: >10min 2: >30min 3: >60min 4: >120min 5: >240min 6: >480min	> 480 minutes
<b>EN 16523-1</b>	Permeation 30% Hydrogen Peroxide	different classes 1: >10min 2: >30min 3: >60min 4: >120min 5: >240min 6: >480min	Minimum 121 minutes
<b>EN 374-4</b>	Degradation 37% Formaldehyde	N/A	Mean degradation 28.6%
<b>EN 374-4</b>	Degradation n-Heptane	N/A	Mean degradation 42.3%
<b>EN 374-4</b>	Degradation 40% Sodium Hydroxide	N/A	Mean degradation -34.7%
<b>EN 374-4</b>	Degradation 30% Hydrogen Peroxide	N/A	Mean degradation 19.9%
<b>EN 374-5</b>	Penetration by blood borne pathogen Protection against bacteria and fungi Protection against viruses	No penetration	Pass  Pass  Pass
<b>EN 420:2003 +A1:2009</b>	Chemical innocuousness	<1mg/kg of each PAH listed	Pass
<b>EN 420:2003 +A1:2009 length</b>	Length	hand size    min. length (mm)	hand size    Left    Right (mm)
		6            220	6            245    250
		7            230	7            250    250

		8            240 9            250 10          260	8            245    251 9            259    256 10          260    255  Pass
<b>EN 420:2003 +A1:2009 Dexterity</b>	Dexterity	Performance level 1: 11mm 2: 9.5mm 3: 8.0mm 4: 6.5mm 5: 5.0mm	Level 5