

## **SECTION 7 –USER INFORMATION AND PRODUCT MARKING**

*(Include a copy of your user information and product marking/labels here. Ensure that you have fully addressed all requirements from the applicable harmonised standard or specification plus in addition to those of PPE Regulation (EU) 2016/425 Annex II Clause 1.4 – see section 6 of this file. Remember – always ensure that the instructions are clear and free from ambiguity).*

### **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 EC certificate of conformity issued by SATRA Technology Europe Ltd (Notified Body No.: 2777) located at Bracetown Business Park, Clonee, County Meath, Dublin 15, Ireland.

#### **2.2 mil (2.7g – 3.1g) Powder Free Nitrile Examination Gloves**

**Product code: PFSN-FTCB, PFSN-FTP, PFSN-FTRB, PFSN-FTSB, PFSN-FTW, PFSN-FTO and PFSN-FTCR**

Article No.	Brand Name	Size*	Remarks
93775, 92885, 92965, 92975, 92885, 92995, 92985	MAXTER	EX-SMALL Hand Size (6-7)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
93776, 92886, 92966, 92976, 92886, 92996, 92986	MAXTER	SMALL Hand Size (7-8)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
93777, 92887, 92967, 92977, 92887, 92997, 92987	MAXTER	MEDIUM Hand Size (8-9)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
93778, 92888, 92968, 92978, 92888, 92998, 92988	MAXTER	LARGE Hand Size (9-10)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.
93779, 92889, 92969, 92979, 92889, 92999, 92989	MAXTER	EX-LARGE Hand Size (10-11)	Type B for chemical protection and provide protection against bacteria, fungi and viruses.

\* 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



The permeation performance of the gloves against chemicals

- Level 2 ó n-Heptane (J)
- Level 6 - Sodium Hydroxide 40% (K)
- Level 5 ó Formaldehyde 37% (T)
- Level 1 - Hydrogen Peroxide 30% (P)

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

- Protection against bacteria and fungi óPass
- Protection against viruses- Pass

ISO 374-5:2016



**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)  
P.O. Box 30 (Särkiniementie 3), 00211 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 to prevent discoloration. 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 users' hands against 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 420 length</b>	Length	hand size min. length (mm) 6 220 7 230 8 240 9 250 10 260	hand size Left Right (mm) 6 245 250 7 250 250 8 245 251 9 259 256 10 260 255*
<b>EN 420 Dexterity</b>	Dexterity	Performance level 1: 11mm 2: 9.5mm 3: 8.0mm 4: 6.5mm 5: 5.0mm	Level 5
<b>EN 374-2</b>	Determination of resistance of water leak	No leak	No leaks detected. Pass
<b>EN 16523-1</b>	Permeation 30%Hydrogen Peroxide	different classes 1: >10min 2: >30min 3: >60 min 4: >120min 5: >240min 6: >480min	Minimum 21 minutes
<b>EN 16523-1</b>	Permeation n-Heptane	different classes 1: >10min 2: >30min 3: >60 min 4: >120min 5: >240min 6: >480min	Min 34 minutes
<b>EN 16523-1</b>	Permeation 40% Sodium Hydroxide	different classes 1: >10min 2: >30min 3: >60 min 4: >120min 5: >240min 6: >480min	> 480 minutes
<b>EN 16523-1</b>	Permeation 37% Formaldehyde	different classes 1: >10min 2: >30min 3: >60 min 4: >120min 5: >240min 6: >480min	> 240 minutes

<b>EN 374-4</b>	Degradation 30% Hydrogen peroxide	N/A	Mean degradation 48.7%
<b>EN 374-4</b>	Degradation 37% Formaldehyde	N/A	Mean degradation 16.7%
<b>EN 374-4</b>	Degradation n-Heptane	N/A	Mean degradation 51.4%
<b>EN 374-4</b>	Degradation 40% Sodium Hydroxide	N/A	Mean degradation -36.1%
<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

Notes: \* Deviating length as the gloves are for examination purpose as well which required to meet minimum 240mm only. With the length of 255mm, the 2.2 mil (2.7g ó 3.1g) Powder Free Nitrile Examination Gloves shall be able to provide the necessary protection for hand as the intended purpose.

**Annex to the Instruction For Use for the product MAXTER 2.2 mil (2.7g – 3.1g) Powder Free Nitrile Examination Gloves, SECTION 7 – USER INFORMATION AND PRODUCT MARKING**

**Importer:** Mercator Medical S.A., ul. H. Modrzejewskiej 30, 31-327 Krakow, POLAND.

[www.mercatormedical.eu](http://www.mercatormedical.eu)