

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 Darul Ehsan, Malaysia.

PRODUCT DESCRIPTION

Non Sterile Powder Free Latex Examination Gloves are made from 100% natural rubber, ambidextrous, beige coloured and for single use. It is treated with polymer or chlorinated 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

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.

Article No.	Brand Name	Size*	Remarks
98225, 28255, 29225, 29985, 88225, 88235	MAXTER	EX-SMALL Hand Size (6)	Type C for chemical protection and provide protection against bacteria, fungi and viruses.
98226, 28256, 29226, 29986, 88226, 88236	MAXTER	SMALL Hand Size (7)	Type C for chemical protection and provide protection against bacteria, fungi and viruses.
98227, 28257, 29227, 29987, 88227, 88237	MAXTER	MEDIUM Hand Size (8)	Type C for chemical protection and provide protection against bacteria, fungi and viruses.
98228, 28258, 29228, 29988, 88228, 88238	MAXTER	LARGE Hand Size (9)	Type C for chemical protection and provide protection against bacteria, fungi and viruses.
98229, 28259, 29229, 29989, 88229, 88239	MAXTER	EX-LARGE Hand Size (10)	Type C 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

ISO 374-1:2016/Type C



The permeation performance of the gloves against chemicals

Level 3 - Sodium Hydroxide 40% (K)

Level 1 – Sulphuric Acid 96% (L)

Level 5 – Formaldehyde 37% (T)

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

Protection against bacteria and fungi –Pass

Protection against viruses- Pass

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, located at P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland

STORAGE CONDITIONS

Do not store Non Sterile Powder Free Latex 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 Latex Examination Gloves should be shielded from exposure to direct sunlight or fluorescent lighting to prevent discoloration. Improper storage of Non Sterile Powder Free Latex Examination Gloves will result in decreased shelf life and compromised efficiency.

USE

These gloves are designed to protect user's 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

Safe use of this glove by or on latex sensitized individuals has not been established.

WARNING

Isolated cases of allergic reactions to latex rubber or powder have been reported. If you experience a reaction to this product, discontinue use immediately and consult your physician. This product contains Natural Rubber Latex which may cause allergic reactions in some individuals.

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:

Method	Description	Requirements	Result																														
EN 420 length	Length	<table><tr><th>hand size (mm)</th><th>min. length</th></tr><tr><td>6</td><td>220</td></tr><tr><td>7</td><td>230</td></tr><tr><td>8</td><td>240</td></tr><tr><td>9</td><td>250</td></tr><tr><td>10</td><td>260</td></tr></table>	hand size (mm)	min. length	6	220	7	230	8	240	9	250	10	260	<table><tr><th>hand size (mm)</th><th>Left</th><th>Right</th></tr><tr><td>6</td><td>255</td><td>257</td></tr><tr><td>7</td><td>258</td><td>261</td></tr><tr><td>8</td><td>255</td><td>253</td></tr><tr><td>9</td><td>263</td><td>255</td></tr><tr><td>10</td><td>266</td><td>267</td></tr></table>	hand size (mm)	Left	Right	6	255	257	7	258	261	8	255	253	9	263	255	10	266	267
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			Pass																														
EN 420 Dexterity	Dexterity	Performance level 1: 11mm 2: 9.5mm 3: 8.0mm 4: 6.5mm 5: 5.0mm	Level 5																														
EN 374-2	Determination of resistance of water leak	No leak	No leaks detected. Pass																														
EN 16523-1	Permeation 40% Sodium Hydroxide	different classes 1: >10min 2: >30min 3: >60 min 4: >120min 5: >240min 6: >480min	69 minutes																														
EN 16523-1	Permeation 96% Sulphuric Acid	different classes 1: >10min 2: >30min 3: >60 min 4: >120min 5: >240min 6: >480min	Minimum 20 minutes																														
EN 16523-1	Permeation 37% Formaldehyde	different classes 1: >10min 2: >30min 3: >60 min 4: >120min 5: >240min 6: >480min	Between 241 minutes to 360 minutes																														
EN 374-4	Degradation	N/A	Mean degradation																														

	40 % Sodium Hydroxide		-21.7 %
EN 374-4	Degradation 96% Sulphuric Acid	N/A	Mean degradation 95.8 %
EN 374-4	Degradation 37% Formaldehyde	N/A	Mean degradation -21.4%
EN 374-5	Penetration by blood borne pathogen Protection against bacteria and fungi Protection against viruses	No penetration	Pass Pass Pass
EN 420	Chemical innocuousness (Amount of aqueous extractable proteins)	50 µg/g	Mean 16.1 µg/g

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Annex to the Instruction For Use for the product MAXTER Non Sterile Powder Free Latex Examination Gloves,
INSTRUCTION FOR USE

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

www.mercatormedical.eu

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