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# MATERIAL AND SAFETY DATA SHEET

## **Powder Free Chlorinated Latex Examination Gloves**

## **Factory:**

**Maxter Glove Manufacturing Sdn Bhd** 

Lot 6070, Jalan Haji Abdul Manan, 6<sup>th</sup> Miles Off Jalan Meru, 41050 Klang, Selangor DE Malaysia

Tel: (603) 33929888 Fax: (603) 33923328

## SECTION 1 DESCRIPTION OF PRODUCT

1.1 Device Family: Powder Free Latex Examination Gloves

Classification: Class I, Non-sterile

Conformity : Annex VII, self declaration of conformity

Powder free latex examination glove is classified as Class I medical device as per Rule 1, Annex IX of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC.

## 1.2 Brief Description

The powder free latex examination glove is made from 100% natural rubber, ambidextrous and non-sterile It is treated with Chlorine which is to facilitate the user in donning the glove and as well as to prevent the glove surface from sticking to each other.

## 1.3 Intended Use

The powder free latex examination glove is a medical device, which protects the hand of the user.

The main function of wearing gloves is to protect the wearer against contamination of infectious materials particularly viruses, bacteria, infected blood and body fluids. Thus, the single most important criterion



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in gloves selection is barrier protection, as defined by all users, including physicians, dentists, medical and non-medical workers and researchers.

The next most important criterion are strength, fit, comfort and dexterity, that is the ability for the glove to stretch, remain soft and comfort to the hand due to the thickness and elastomeric nature of the latex glove.

It is intended for single use only.

The powder free latex examination gloves are usually used for conducting medical examination, dentistry, clinical examination, diagnostic and therapeutic procedures, and also for laboratory purposes.

## SECTION 2 PHYSICAL DATA

Meet with the requirements of ASTM D3578:2005 Standard Specification for Rubber Examination Gloves, EN455-1:2000, EN455-2:2009+A2:2013 and EN455-3:2006 Medical Gloves for Single Use.

Width  $95 \pm 10 \text{ mm (size medium)}$ 

Length 240 mm minimum

Thickness 0.08 mm minimum (providing tactile sensitivity)
Tensile Strength (unaged) 18.0 MPa minimum (providing superior strength)

Ultimate elongation (unaged) 650% minimum
Tensile Strength (aged) 14.0 MPa minimum
Ultimate elongation (unaged) 500% minimum

Watertightness Substantially impermeable to water vapour and liquid

water providing an excellent biological barrier. Double

gloving is recommended for reduced risk.

## SECTION 3 HEALTH HAZARD INFORMATION

Biocompatibility data Guinea Pig Sensitization (Buehler) -

Did not indicate a potential for dermal irritation or allergic

contact sensitization.

Repeated Insult Patch Test -

Did not indicate a potential for dermal irritation or allergic

contact sensitization.



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## SECTION 4 FIRST AID MEASURES

Skin Warning: Isolated cases of allergic reactions to latex rubber have

been reported. If you experience a reaction to this product, discontinue use immediately and seek for medical help. This product contains Natural Rubber Latex which may cause allergic

reactions in some individuals.

Other components used in making gloves may also cause allergic

reactions in some users.

Note: Leaching and washing processes undertaken during the manufacture of powder free gloves have significantly reduced protein level and residual chemical levels in gloves.

## SECTION 5 HANDLING AND STORAGE

Storage Store in cool, dry place, avoid excessive heat (40 ° C, 104 ° F).

Open box should be shielded from exposure to direct sun or

fluorescent lighting.

Disposal Material may be recycled or disposed of in accordance to local

disposal regulations.

Fire Hazard Flammable. Suitable extinguishing media are: - dry extinguishing

media, foam.

## SECTION 6 SPECIAL PROTECTION INFORMATION

In accordance to EN 374-3: 2003 Permeation by Chemicals

40% Sodium hydroxide Level 6