



M A X T E R
GLOVE MANUFACTURING SDN BHD
(229862-H)

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
E-MAIL: maxter@tm.net.my
www.maxter.com.my

MATERIAL AND SAFETY DATA SHEET

Powder Free Nitrile Examination Gloves

Factory:

Maxter Glove Manufacturing Sdn Bhd

Lot 6070, Jalan Haji Abdul Manan,

6th 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 Nitrile Examination Gloves
Classification : Class I, Non- sterile
Conformity : Annex VII, self declaration of conformity

Powder free nitrile 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 nitrile examination glove is made from 100% nitrile synthetic rubber (NBR Protein Free), 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 nitrile 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 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 nitrile glove.

It is intended for single use only.

The powder free nitrile 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 D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application and EN455-1:2000, EN455-2:2009+A2:2013 and EN455-3:2006 Medical Gloves For Single Use.

Width	95 ± 10 mm (size medium)
Length	240 mm minimum
Thickness	0.05 mm minimum (providing tactile sensitivity)
Tensile Strength (unaged)	14 MPa minimum (providing superior strength)
Ultimate elongation (unaged)	500% minimum
Tensile Strength (aged)	14 MPa minimum
Ultimate elongation (aged)	400% 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.
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Repeated Insult Patch Test -
Did not indicate a potential for dermal irritation or allergic
contact sensitization.

SECTION 4 FIRST AID MEASURES

Skin 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
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 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
n-Heptane	Level 5