



**SUPERMAX**  
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## MATERIAL AND SAFETY DATA SHEET

### Aurelia Sonic Powder Free Nitrile Examination Gloves

#### Factory:

**Supermax Glove Manufacturing Sdn Bhd**

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#### 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

Aurelia Sonic 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 (NR 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, EN455-2, EN455-3 and EN455-4 Medical Gloves For Single Use.

Width	95 ± 10 mm (size medium)
Length	240 mm minimum
Thickness	0.05 mm minimum (providing tactile sensitivity)
Force at Break (unaged)	Minimum 6N for the median value (providing superior strength)
Ultimate elongation (unaged)	500% minimum
Force at Break (aged)	Minimum 6N for the median value
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.

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.



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QA & Regulatory Affairs Manager

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