Synmax Vinyl Hybrid Medical Exam Gloves

(contains nitrile, see page 3)

Black | Medical Grade | Powder Free | FDA 510(k) | Latex Free

Synmax Examination Gloves

Revolutionary new formula of vinyl-based hybrid material, containing nitrile, uses latex-like properties with elastic and strong "bones" of gloves. They offer enhanced tactile sensitivity and a practical barrier of protection for a wide range of applications. They are also a good alternative for those suffering from TypeI allergies.















Features

- Brand new product
- · DOP, DEHP-free
- No latex proteins, low allergy potential
- · Comfortable conforming latex-like fit
- Effective barrier and extra strength
- · Enhanced tactile sensitivity
- Economical protection
- Resistance to acid, alkali and oil
- 100 gloves per box

Quality standards

- · Complies with EN 455 and EN 374
- · Complies with ASTM D5250 (USA Related Product)
- Tensile Strength: 18MPa
- Palm Thickness: 0.08 mm minimum
- Finger thickness: 0.09 mm minimum (3.5-4 mil)
- Weight: 5.0 gm (size medium)
- · Length: 230 mm minimum

Technical information

Туре	Powder-free, unsterile
Material	Compound of Vinyl-based Hybrid
Colour	Black
Model	Ambidextrous, with rolled rim
Storage	Protect from heat, humidity, strong light and ozone
Size/overall length as per EN 455-2	S, M, L and XL 240 mm (≥ 230mm for USA)
Impermeability as per EN 455-1	AQL 1.5
Durability, in original package if stored as per din 7716, ISO 2230	Min. 5 years





























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510(k) Premarket Notification



Device Classification Name Vinyl Patient Examination Glove

510(K) Number K132201

Device Name SYNMAX SYNTHETIC EXAMINATION VINYL GLOVES, POWDER FREE,

BLUE COLOR

Applicant ZIBO INTCO MEDICAL PRODUCTS CO., LTD.

12390 EAST END AVE.

Chino, CA 91710

Applicant Contact John Zhao

Correspondent ZIBO INTCO MEDICAL PRODUCTS CO., LTD.

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Regulation Number
Classification Product
Code

John Zhao

880.6250

LYZ

 Date Received
 07/16/2013

 Decision Date
 11/27/2013

Decision Substantially Equivalent (SESE)

Regulation Medical General Hospital Specialty

510k Review Panel General Hospital
Summary Summary
Type Traditional

Reviewed By Third Party No **Combination Product** No

- ✓ Disposable gloves create a barrier between your hands and objects you are handling to keep hands clean and protected and keep oils and dirt on your hands from transferring to the objects. Single-use gloves.
- ✓ THICK, HEAVY-DUTY RESILIENCE: Crafted with Compound of vinyl-based Hybrid, these versatile gloves are stronger than nitrile or latex while still giving you the dexterity and control you need for needles or equipment. They are powder-free, ambidextrous and offer a stretchy & comfy fit for both men and women. These gloves can suit any need because they come in compact, stackable boxes, they're easy to store, and they're also disposable for quick, safe, and simple clean up.
- ✓ NO LATEX, NO POWDER: Avoid potential allergies and discomfort with our gloves without the use of latex or powder, your body will be kept in optimal safety from potential allergens.