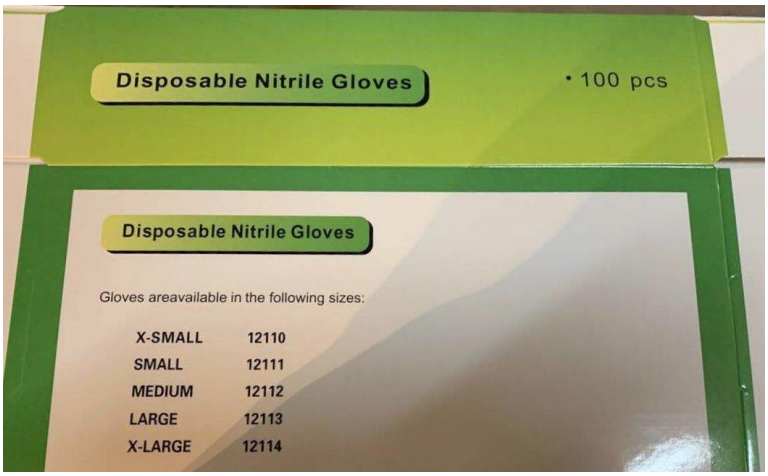
Blue Nitrile Gloves - Powder-Free
FDA Medical Grade Patient Examination Gloves

Blue Nitrile Gloves - Powder-Free FDA Medical Grade Patient Examination Gloves per Regulation Number 21 CFR 880.6250. These Medical Blue Nitrile Gloves are constructed from lightweight nitrile with fully textured grip, measuring 12 inches from fingertip to glove cuff. Medical-grade nitrile gloves offer dexterity and tactile sensitivity for daily tasks including non-sterile medical procedures, lab work and more.



These powder-free disposable blue nitrile medical examination gloves are latex-free for those allergic to natural rubber latex. Our blue nitrile exam gloves meet Regulation Number 21 CFR 880.6250. Medical Grade, Disposable, Powder Free, Latex Rubber Free, Heavy Duty, Textured, Medical and Food Safe.

- Available in Small, Medium, and Large Sizes.
- Color - Blue
- Quantity in 1 Box - 100 Gloves = 50 pairs in 1 Box

Order Online at:
https://www.professionalplastics.com/Blue-Nitrile-Gloves-Powder-Free-FDA

Email: sales@proplas.com

USA (888) 995-7767 – Singapore +65 6266-6193 – 台湾 Taiwan +886 (3) 5357850

Scroll Down for Product Certificates & Regulations

一次性医用丁腈检查手套 FDA 证书（1）

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 18, 2015

HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD
C/O Mr. Ray Wang
Beijing Believe Tech. Service Co., LTD
1-202, Build 3, Beijing New World, No. 5 Chaoyang Rd.
Chaoyang District, Beijing, 100024
China

Re: K150340
Trade/Device Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: NITRILE Patient Examination Gloves (Power Free)
Regulatory Class: I
Product Code: LZA
Dated: May 14, 2015
Received: May 18, 2015

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

MDD 93/42/EEC 符合性声明
（欧盟 CE 证件）

CE DECLARATION OF CONFORMITY

Manufacturer

Name: Hebei Titans Hongsen Medical Technology Co., Ltd

Address: Eastern Industrial Zone, Nangong City, Xingtai City, Hebei, China

Declares that the MDD described hereafter

Products name and Model:

Disposable Nitrile Examination Gloves

XS, S, M, L and XL

Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC

Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex IX

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, NISO14971:2012

Applied harmonized standards: EN455-1: 2000, EN455-2: 2015, EN455-3: 2015, EN ISO14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC

The CE declaration of conformity is issued under the sole responsibility of Hebei Titans Hongsen Medical Technology Co., Ltd

The products can be placed the following CE mark.

CE

Signature: Feng Shang yan

Date: April 23, 2019

Quality Supervision Organization