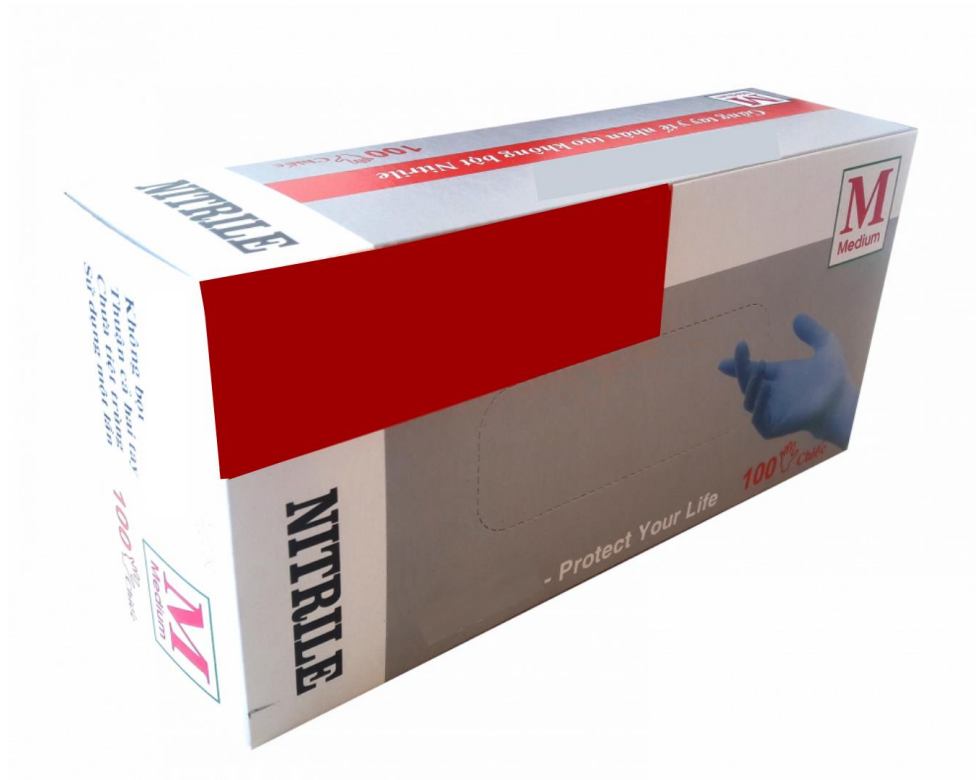
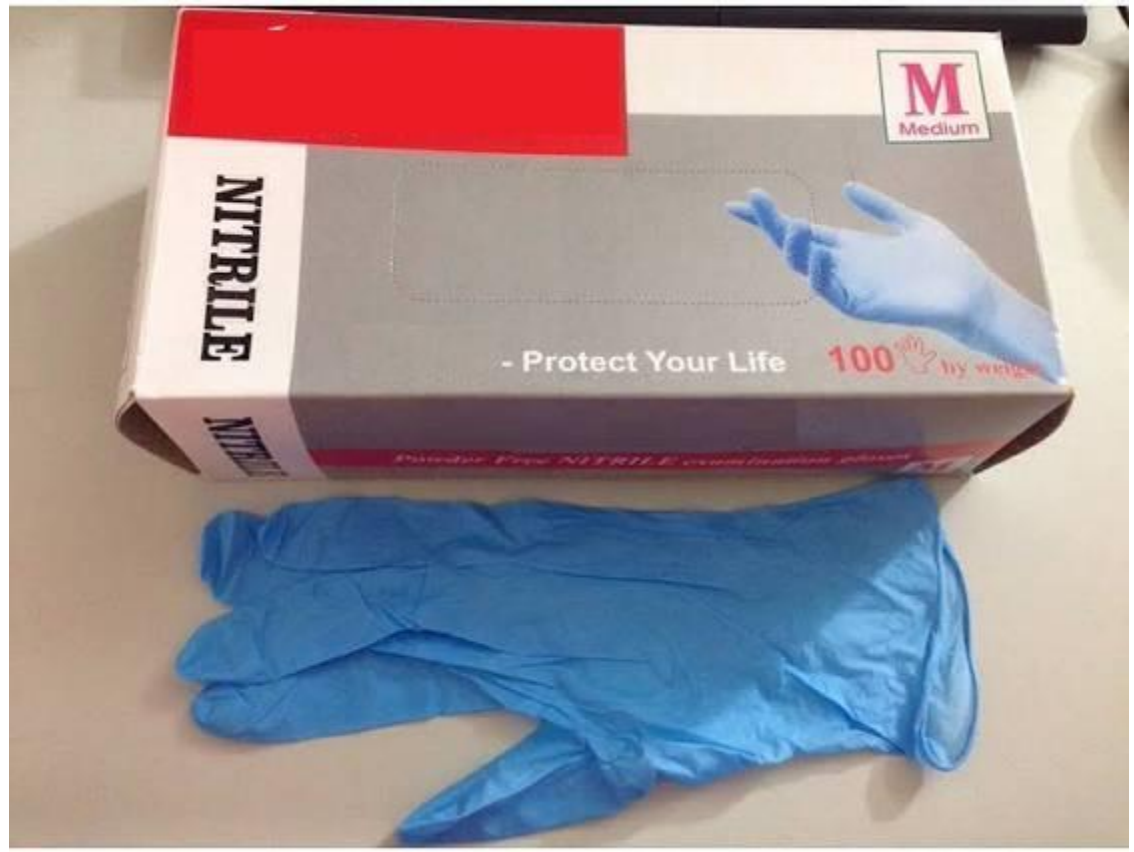
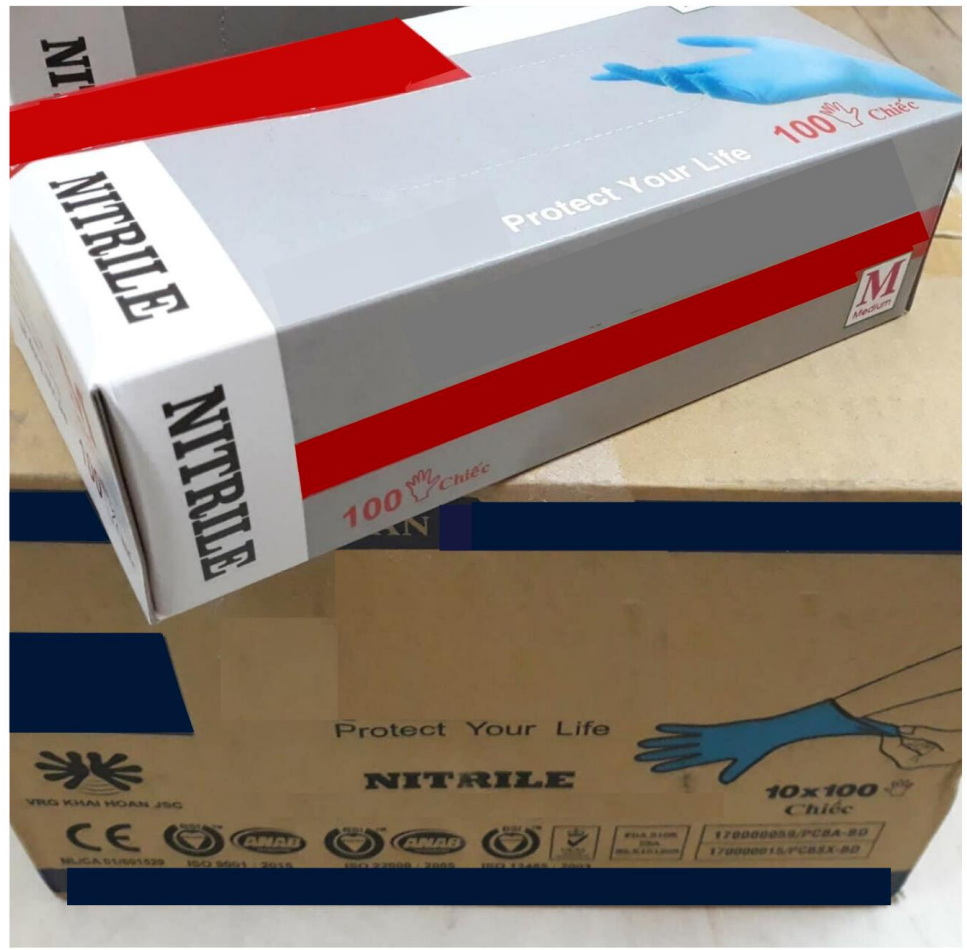

NITRILE
M
Medium
- Protect Your Life
100 Pc's/Box


M
Medium
NITRILE
- Protect Your Life
100


NITRILE
Protect Your Life
100 Chiếc
M
Medium
NITRILE
100 Chiếc
Protect Your Life
NITRILE
10x100
Chiếc

# NITRILE GLOVES

## POWDER FREE

### Functional Benefits

Protection from unwanted and dangerous substances
Beaded cuff ensures easy donning and prevent roll down
Superior strength with better puncture resistance
Full textured or Finger Tip textured enhances wet and dry grip
Thinner gauge improves tactile sensitivity
Custom design enhances comfort and fit
Provide an alternative solution for individuals who are allergic to natural rubber latex

### Product Specifications

| | |
|---|---|
| Material | Synthetic Nitrile latex. |
| Type | Non-Sterile Powder-Free.<br>Ambidextrous; Finger Tip Textured; Beaded Cuff; White or Coloured (Blue, Light Blue, ...) |
| Quality Standards | Conforms to ASTM D6319<br>Manufactured under ISO9001: 2008, ISO 13485:2003. ISO 22000:2005 Quality Management System.<br>Manufactured from 100% nitrile (Acrylonitrile-Butadiene) |
| Gloves Size | Extra-small, Small, Medium, Large, Extra-large.<br>Marked in the check box on the shipping carton with black ink. |
| Storage | Store in a dry and cool place, the temperature not higher than 38°C. |
| Shelf-fife | 3 years from the date of manufacturing. |

### PHYSICAL DIMENSIONS

| DIMENSIONS | Standards | |
|---|---|---|
| | VRG KHAI HOAN | ASTM D6319 |
| Length (mm) | 230 min | 220 min (XS, S)<br>230 min (M, L, XL) |
| Width (mm) | 75 ± 5 (XS)<br>85 ± 5 (S)<br>95 ± 5 (M)<br>105 ± 5 (L)<br>115 ± 5 (XL) | 70 ± 10 (XS)<br>80 ± 10 (S)<br>95 ± 10 (M)<br>110 ± 10 (L)<br>120 ± 10 (XL) |
| Thickness-Single wall (mm) | Fingers : 0. 08 mm min<br>Palm : 0.06 mm min | Fingers : 0.050 mm min<br>Palm : 0.05 mm min |

### PHYSICAL PROPERTIES AND BIOCOMPATIBILITY

| | | |
|---|---|---|
| Tensile | Tensile strength (MPA)<br>Before aging: 18Mpa min<br>After aging: 20Mpa min<br><br>Elongation at break (%)<br>Before aging: 600% min<br>After aging: 500% min | Tensile strength (MPA)<br>Before aging: 14Mpa min<br>After aging: 14Mpa min<br><br>Elongation at break (%)<br>Before aging: 500% min<br>After aging: 400% min |
| Powder Content | 2 mg/glove maximum | |
| Protein Content | Free Protein | |

EMERGO EUROPE

26 May 2009

Dear

I am writing to inform you that today, we have notified by registered mail the Dutch Competent Authority.

With this notification, has met the requirements of Article 14 of the Medical Devices Directive, 93/42/EEC for the following devices:

- **Powder Examination Gloves**
- **Powder-Free Examination Gloves**

As of today and without any further notice from the respective Competent Authorities, can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande
President & CEO



Emergo Europe Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570 Fax: +31.70.346.7299

EMERGO EUROPE

# CE Registration Certificate

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received Medical Device Registrations on the following date:

**26 May 2009**
**See attached product listing**

**Emergo Europe Registration Number: NL/CA01/601529**

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the Medical Devices fulfill the applicable requirements of Directive 93/42/EEC.

June 2009

Rene van de Zande
President & CEO
Emergo Europe

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 2 2 2010

Re: [redacted]
Trade/Device Name: Powdered Latex Examination Gloves (Non-Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: January 14, 2010
Received: January 19, 2010

Dear

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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

bsi.

By Royal Charter

# Certificate of Registration

GOOD MANUFACTURING PRACTICE – GMP

This is to certify that:

Holds Certificate Number: **BSIVN 1313/2019**

and operates a Good Manufacturing Pratice which complies with the requirements of GMP-HACCP (CAC/RCP 1-1969, Rev.4-2003) the following scope:

**The manufacture and distribution of:**
**- Non-sterile, powder, powder free natural latex examination gloves.**
**- Non-sterile, powder free nitrile examination gloves.**

For and on behalf of BSI: Le Duyen Anh, Managing Director Vietnam

Original Registration Date: **10/06/2019**
Effective Date: **10/06/2019**
Latest Revision Date: **10/06/2019**
Expiry Date: **09/06/2022**

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By Royal Charter

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Holds Certificate Number: **FM 548618**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**The manufacture and distribution of:**
**Non-sterile, powder, powder free natural latex examination gloves;**
**Non-sterile, powder free nitrile examination gloves.**

For and on behalf of BSI: Chris Cheung, Head of Compliance & Risk – Asia Pacific

Original Registration Date: **01/06/2009**
Latest Revision Date: **30/05/2018**

Effective Date: **01/06/2018**
Expiry Date: **31/05/2021**



...making excellence a habit.™

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By Royal Charter

# Certificate of Registration

SOCIAL ACCOUNTABILITY SYSTEM - SA 8000:2014

This is to certify that:

Holds Certificate Number: **SA 598117**

and operates a Social Accountability System which complies with the requirements of the Social Accountability Standard SA 8000:2014 for the following scope:

**The manufacture and distribution of non-sterile powder, powder free latex and nitrile examination glove through the process of receiving rubber latex/ nitrile, compounding, coagulating, vulcanising, leaching, slurry/ chlorine dipping, drying, testing, packing and despatch.**

**Outsourced processes: Nil**
**Contracted processes: Nil**

For and on behalf of BSI: Managing Director, BSI India, Venkataram Arabolu

Original Registration Date: **19/11/2013**
Latest Revision Date: **11/11/2019**

Effective Date: **19/11/2019**
Expiry Date: **18/11/2022**



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BSI, The MIRA Corporate Suites (A-2), Plot 1 and 2, Ishwar Nagar, Mathura Road, New Delhi 110 065
A Member of the BSI Group of Companies