SUPERIEUR®
SIMPLY SUPERIOR

Nitrile Examination Gloves

Powder Free

CD@CNGA.us
LOI/POF needed
Bank fund verification
With attorney
POL available after call

Feature

- Flexible and ductile
- Finger textured
- Online chlorinated/ Polymer coated
- Latex free
- Ambidextrous

Nitrile Examination Gloves

Product Information

Disposable Nitrile Examination Gloves, Powder Free, Non-sterile

Primary Material	: Acrylonitrile Butadiene Synthetic Rubber Latex
Latex Protein Content	: Latex-free
Color	: White/ Black/ Blue
Size	: Extra-small, Small, Medium, Large And Extra-large
Design And Feature	: Ambidextrous, Straight Fingers, Finger-textured, Beaded Cuff, Polymer Coated/ Online Chlorinated
Packing	: 100 Pieces Gloves Per Dispenser, 10 Dispensers Per Carton

Medical Use

Food Contact Use

General Use

Physical Dimensions

Dimensions		Standards	
		Supérieur	ASTM D6319 / EN 455
Length (mm)		240 min	230 min / 240 min
Width (mm)	Extra-Small	75 ± 10	75 ± 10
	Small	80 ± 10	80 ± 10
	Medium	95 ± 10	95 ± 10
	Large	110 ± 10	110 ± 10
	Extra-large	≧ 110	≧ 110
Thickness-single wall (mm)	Palm	Min. 0.05	Min. 0.05
	Finger	Min. 0.05	Min. 0.05

Physical Properties

Criteria		Supérieur	ASTM D6319 / EN 455
Elongation (%)	Before Aging	Min. 500	Min. 500
	After Aging	Min. 400	Min. 400 / Min. 500
Tensile Strength	Before Aging	Min. 18 (MPa)	Min. 14 (MPa) / 6.0 N
	After Aging	Min. 14 (MPa)	Min. 14 (MPa) / 6.0 N

Manufactured under ISO 9001 & ISO 13485 Quality Systems

PRODUCT PRESENTATION

SUPÉRIEUR®
SIMPLY SUPERIOR

Nitrile Vynil Examination Gloves Powder-Free

*** The tested sample / part is marked by an arrow if it's shown on the photo. ***

CT/2018/70053

** End of Report **

Ref.: SGS TEST REPORT

Sizes:

S L M XL

CERTIFICATIONS

FDA

The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments, an agency responsible for the control and safety of food and drugs.

FDA

The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments, an agency responsible for the control and safety of food and drugs.

CG mark

"Japan Association for Cooking Gloves" is to promote appropriate use to ensure safety of cooking gloves.
It has established a standards according to three kinds of material: "PVC gloves" "NBR gloves" and "Latex gloves".

ISO 9001

ISO 9001 specifies requirements for a quality management system when an organization:
(a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
(b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

ISO 13485

ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

NSF International Protocol P155

NSF International, is a not for profit, non governmental organization. They are the leading global supplier of public health and safety based risk management services.
This protocol covers disposable single-task gloves typically used for food handling, preparation, and service tasks. This protocol establishes criteria for product quality in terms of toxicology, physical properties, barrier resistance, and sanitation.

ISO 374-1 : 2016/Type C

ISO 374-5 : 2016

FDA CERTIFICATE

U.S. FOOD & DRUG ADMINISTRATION

June 11, 2018

Ever Global (Vietnam) Enterprise Corp
% Elizabeth Deng
Coordinator
5748 Eaglewood Place
Rancho Cucamonga, California 91739

Re: K171422
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: April 27, 2018
Received: April 30, 2018

Dear Elizabeth Deng:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171422

Device Name
Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color

Indications for Use *(Describe)*
The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FDA WEBSITE

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K171422

510(k) Premarket Notification

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K171422
Device Name	Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color
Applicant	Ever Global (Vietnam) Enterprise Corp Long Thanh Industrial Zone Taman Village Dong Nai Province, VN 810000
Applicant Contact	Jerry Lin
Correspondent	Elizabeth Deng 5748 Eaglewood Place Ranch Cucamonga, CA 91739
Correspondent Contact	Elizabeth Deng
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	05/15/2017
Decision Date	06/11/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement
Type	Abbreviated
Reviewed By Third Party	No
Combination Product	No

CE CERTIFICATION

MDSS

Medical Device Safety Service

Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Sri Trang Gloves (Thailand) Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai
90110 Songkhla
THAILAND

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated September 18, 2019

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2019-09-18

Dr. Philipp Hohenbrink
Senior Consultant
MDSS GmbH

SATRA TECHNOLOGY

Issued to:

VRG Khai Hoan JSC
Cau Sat Hamlet
Lai Hung Commune
Bau Bang District
Binh Duong Province
Vietnam

Notified Body: 2777

SATRA customer number: P1434

EU Type-Examination Certificate

Certificate number: 2777/11582-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference: PFNBR

Description: Non-sterile powder free nitrile examination gloves

Sizes: XS/6, S/7, M/8, L/9, XL/10

Classification:

EN ISO 374-1: 2016 / Type B	Level	EN ISO 374-4:2013 % Degradation
40% Sodium hydroxide (K)	6	-13.2
30% Hydrogen peroxide (P)	4	5.3
37% Formaldehyde (T)	6	4.6
EN ISO 374-5: 2016		
Protection against Bacteria and fungi	Pass	
Protection against viruses	Pass	

From: PPE <ppe@satra.com>
Subject: FW: Urgent: Please confirm validity of this CE Certificate
Date: 28 May 2020 at 17:00:08 CEST
To: [redacted]

Good Afternoon,

Many thanks for your enquiry.

I can confirm that the certificate you have supplied is genuine and was issued by SATRA.

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

Kind regards

Donna Jawo
Business Development Consultant

SATRA TECHNOLOGY

PLEASE NOTE: All samples for testing should be sent to the following address:
SATRA Technology Centre, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, UK + 44 1536 410000
www.satra.co.uk

For details of forthcoming SATRA seminars on the European Regulation please see:
https://www.satra.com/ppe_regulation_2018

Packaging

100 Gloves per Box

Transportation Boxes

Box Size:

High 25CM

Width 26CM

Length 26CM

10 Small Boxes per Transportation Box

Transportation By Sea and Air