

NITRILE GLOVES

510(k) Premarket Notification

FDA Home Medical Devices Databases



510(k) | De Novo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
 CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

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Device Classification Name	Polymer Patient Examination Glove	510(k) Number	K051333
Device Name	NITRILE EXAMINATION GLOVES, POWDER FREE	Applicant	SHUN THAI RUBBER GLOVES INDUSTRY CO., LTD. 238/1 RATCHADA-PISEK ROAD HUAY-KWANG, BANGKOK 10310 Thailand, TH
Applicant Contact	Anan Jetsadawisut	Correspondent	SHUN THAI RUBBER GLOVES INDUSTRY CO., LTD. 238/1 RATCHADA-PISEK ROAD HUAY-KWANG, BANGKOK 10310 Thailand, TH
Correspondent Contact	Anan Jetsadawisut	Regulation Number	880.5250
Classification Product Code	LZA	Date Received	05/23/2005
Decision Date	07/22/2005	Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital	510k Review Panel	General Hospital
Statement Type	Traditional	Reviewed By Third Party	No
Combination Product	No		

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U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products

Injury Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

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Establishment:			
SHUN THAI RUBBER GLOVES INDUSTRY PUBLIC CO., LTD. 9 MOO 4 KACHED MUANG RAYONG Rayong, TH 21100 Registration Number: 8040818 FEI Number*: 1000154563 Status: Active Date Of Registration Status: 2020			
Owner/Operator:			
SHUN THAI RUBBER GLOVES INDUSTRY PUBLIC CO., LTD. 9 MOO 4 KACHED MUANG RAYONG, Rayong TH 21100 Owner/Operator Number: 8040818			
Official Correspondent:			
David Lennarz Registrar Corp 144 Research Drive Hampton, VA 23666 Phone: 1-757-2240177			
US Agent:			
David Lennarz Registrar Corp 144 Research Drive Hampton, VA US 23666 Phone: 757 2240177 Ext Fax: 757 2240179 Email: David.Lennarz@Registrarcorp.Com			

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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MADE IN THAILAND

Description : Ambidextrous, fully micro texture(T) and beaded cuff

Color : Light blue and sky blue

Standard packing : 100 gloves by weight to a dispenser box and 10 boxes per carton.

Storage : The glove shall maintain their properties when store in a dry condition at temperature not higher than 30oC.

Shelf life : 3 years from date of manufacturing.

Our Nitrile Examination Glove offers top notch protection in synthetic material and is approved by the United States Food and Drug Administration for medical and dental use. For tough durability, the nitrile materials used in our Royal Guard brands are resistant to many chemicals that would otherwise breakdown the compound of other glove types.



Actual Product Brand From Shun Thai That Client Will Receive



NITRILE GLOVES

Nitrile Examination Gloves : ASTM D 6319

1. Watertight test for holes (ASTM D 5151)
2. Dimensions (ASTM D 3767)
3. Physical Properties (ASTM D 412)
4. Powder Content (ASTM D 6124)

Nitrile Examination Gloves : EN 455-2

1. Watertight test for holes (EN 445-1)
2. Dimensions (EN 445-2)
3. Physical Properties (EN 455-2)
4. Powder Content (ASTM D 6124)

Quality Management System

- ISO 9001:2008 -

Certificate of good manufacturing practices of
medical device manufacture -

EC directive 93/42/EEC annex V CE mark on
sterilised latex gloves and examination -

ISO 13485:2003 under CMDCAS

