Wimax Gloves

31/40 KRUNG THEP KRITHA ROAD, THAP CHANG SUB- DISTRICT,
SAPHAN SUNG DISTRICT, BANGKOK

Wimax Group Co.,Ltd was established in 2010, with their initial business focused on retail sale of sporting equipment in specialized stores. As a result of the pandemic crisis in 2020 Wimax made a joint venture agreement with Medical Glove Co., Ltd and JDC Corporation Co., Ltd. to utilize their experience in marketing, sales and export trade to distribute Personal Protective Equipment namely “Examination Gloves” manufactured in Thailand.

Expert Solutions Quality Assured

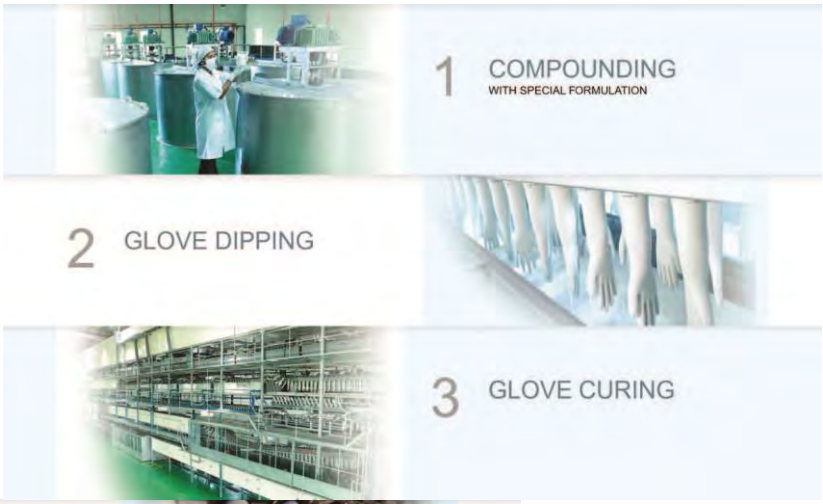
WIMAX GLOVES (THAILAND) CO., LTD "WIMAX" has partnered with MEDICAL GLOVE CO., LTD to facilitate the introduction of a premier high quality fully certified and registered line of protective examination gloves. As a result of the COVID-19 global pandemic it is understood that there will be shortages of quality personal protective equipment "PPE" around the world. WIMAX has decided to devote investment, time, resources, retail experience and their global sales network through teaming with a Medical Glove Company Ltd. a leading manufacturer of Natural Rubber (NR) and Nitrile Butadiene Rubber (NBR) gloves for applications in both medical and general-purpose markets. The core value of the partnership is to provide the best quality protective products at a fair price to those in need.

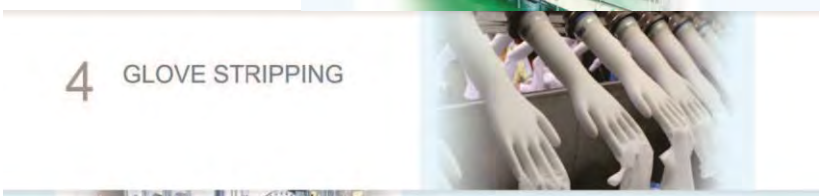
The MG Glove Company is the result of a recent acquisition of a historic market leader in the glove manufacturing industry. The actual MG Glove manufacturing plant located in provinces of Krabi, in the south of Thailand. commenced our operations by producing latex gloves for various medical fields. The factory is surrounded by thousands of acres of rubber tree plantations giving it the advantage of having the natural latex materials in the vicinity at hand.

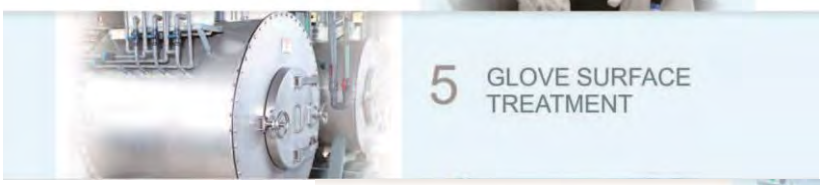
Wimax Gloves

Glove Manufacturing Facilities

We use our in-house special formulation in the compounding process. Our manufacturing facilities are specially designed and built with unique features to produce gloves to meet our customers stringent requirement.







Product Data Sheet – Nitrile Examination Glove Tested For Use with Chemotherapy Drugs

1. Device Trade or Proprietary Name: Nitrile Examination Glove Tested For Use with Chemotherapy Drugs
2. Device Common or Usual Name: Examination Glove
3. Device Classification Name: Nitrile Patient Examination Glove (Powder Free)
4. Description of the Device: Non Sterile, Powder-Free, Nitrile Examination for Use with Chemotherapy
5. Intended Use of the Device: This is the disposable device intended for medical application that is worth examiner's hand to prevent contamination between examiner and patient protect examiner from the following Chemotherapy drugs tested to ASTM with the indicated Breakthrough Detection Times :

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes.

Nitrile Powder Free Examination Glove	Blue
Carmustine (BCNU)	40.00
Cyclophosphamide (Cytoxan)	> 240
Doxorubicin HCl (Adriamycin)	> 240
Etoposide (Topotar)	> 240
Fluorouracil	> 240
Paclitaxel (Taxol)	> 240
Thio-Tepa	177.00
Cisplatin	> 240
Dacarbazine	> 240
Thickness	min 0.1 mm

EN 455 · FDA US-FDA 510(K) · ASTM D6319
EN 420 · CE · ASTM D6124
EN 374 · ASTM D5151
TÜV SÜD · TÜV SÜD

Wimax Gloves

Product Data Sheet – Latex Powder Free Examination Gloves

Characteristics		Inspection Level	Acceptable Quality Level	Reference Standard
Freedom from holes - Barrier		G1	1.5	ASTM 5161 EN 455-1
Visual Defect	● Major Visual ● Minor Visual	G1	2.5 4.0	Industry Practice
Dimensions		S-2	4.0	ASTM D3578 EN 455-2
Physical Properties		S-2	4.0	ASTM D3578 EN 455-2
Risidual Powder Content		N = 5	N/A	ASTM D6124 EN 455-3
Protein Content		N = 3	N/A	ASTM D5712
		N = 8	N/A	EN 455-3

Physical Variable	Size	Specification Limits	Reference Standard
Length (mm)	All sizes	Min 230 Min 240	ASTM D3578 EN 455-2
Pairs Width (mm)	XS S M L	70 ± 10 80 ± 10 95 ± 10 111 ± 10	ASTM D3578
	XL	120 ± 10	In houses / Customer require
	XS S M L XL	≤ 80 90 ± 10 95 ± 10 110 ± 10 ≥ 110	EN 455-2
Thickness (mm) *single wall	All sizes	Middle Finger 0.110 ± 0.02 Palm 0.080 ± 0.02 (3.8-4 mil)	ASTM D3578
		Cuff 0.070 ± 0.02	In houses / Customer require

Properties	Specification Limits		
	Before Aging	After Aging	Reference Standard
Elongation at break	Min 650	Min 800	ASTM D3578
Tensile Strength (MPa)	Min 18	Min 14	
Force at Break (N)	Median 5	Median 6	EN 455-2
Residual Powder Content	Max 2 mg/g		ASTM D8124 EN 455-3
*Protein Content	Max 200μg/dm^2		ASTM D5712
	N/A		EN 455-3

Product Data Sheet – Nitrile Powder Free Examination Gloves

Product Specification					Features
Brand		WIMAX			● Fingertip Textured
Product		Nitrile Examination Glove, Powder Free, Non sterile, Disposable			● Powder Free
					● No Natural Latex
Powder Content		Maximum 2.0mg per Glove			● Lab Chemical Tested
Protein Content		N/A			● Ambidextrous
Size		S - 80±10, M - 95±10, L - 110±10, XL - 115±10			● Blue color
Avg Width (mm)		100 ± 10			● Chlorinated
Avg Weight (g)		3.8 ± 0.3			
Length (mm)		Min 240 (9")			Packaging
Thickness	Cuff	0.070 ± 0.02			100 Pieces Per Box
	Palm	0.080 ± 0.02 (3.8-4 mil)			10 Boxes per Carton (1,000 Pieces)
	Finger	0.110 ± 0.02			
Physical Properties - ASTM					20FCL - 1,300 Cartons (13,000 Boxes)
Parameters		Tensile (MPa)	Elongation Break (%)	Modulus 500% (Mpa)	40FCL - 2,600 Cartons (26,000 Boxes)
		Before Aging			40HQ - 3,200 Cartons (32,000 Boxes)
Medella Result		18	650-670	Max 2.8	
ASTM Requirement		Min 14	Min 650	Max 2.8	Regulatory Compliance
		After Aging			MDD 93/42/EEC
Medalla Result		16	500-650	Max 2.8	FDA 510K / Class 1
ASTM Requirement		Min 14	Min 500	N/A	
Physical Properties - EN					Standards
Parameters		Force Break (N)	Elongation Break (%)		ASTM D6319, D6124-06, D6978-05
		Before Aging			EN ISO 374-1:2016
Medalla Result		9-11	N/A		EN ISO 374-5:2016
ASTM Requirement		Min 9	N/A		ISO 2859-1
		After Aging			EN 374-4:2013
Medella Result		6-10	N/A		EN 420:2003 +A1:2009
ASTM Requirement		Min 6	N/A		EN 388:2016 +A1:2018
Performance					EN 455-2
Inspection		Related Defects	Inspection Level	AQL	
Watertight Test		Moles		1.5	Manufacturing Accreditations
Visual Inspection		Major Defects	G-1	2.5	ISO 9001:2015
		Minor Defects		4.0	ISO 13485:2016
Physical Properties		Tensile	S-2	4.0	GMP Certified
Physical Dimension		Measurement	S-2	4.0	

Certificates

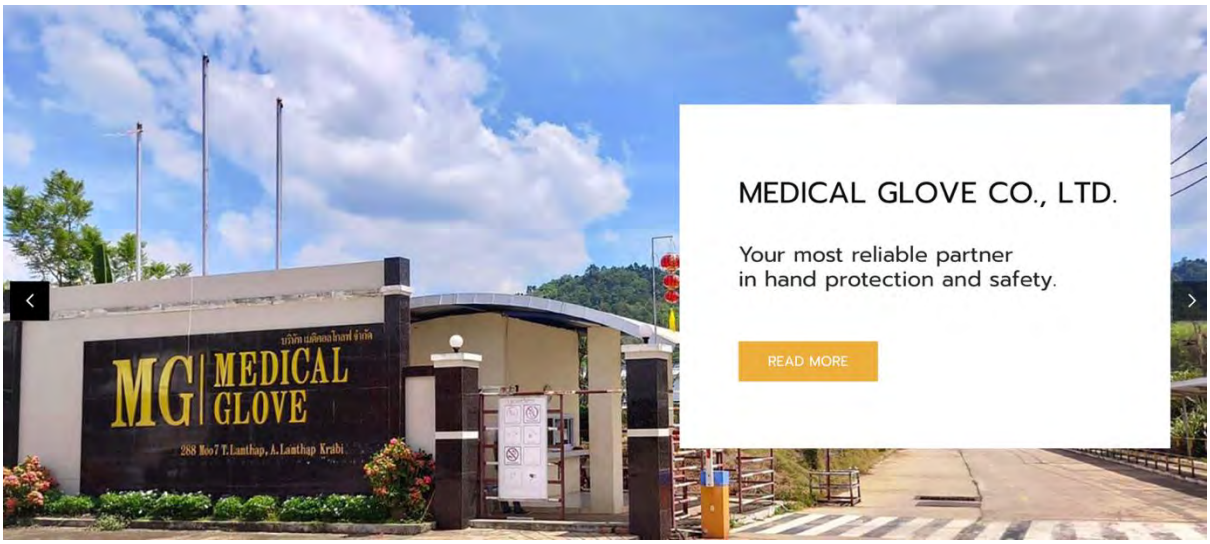
CORPORATE PROFILE

MEDICAL GLOVE CO., LTD

Your most reliable partner in hand protection and safety.

WHO ARE WE

Medical Glove is a newly established medical glove manufacturing company with manufacturing plants located in provinces of Krabi, south of Thailand.



Certificates

MEDICAL MANAGEMENT SYSTEM CERTIFICATION STATUS

1. QUALITY MANAGEMENT SYSTEM CERTIFICATION BY BSI

   - ISO 13485: 2016: Certification Number; MD 716521
   - ISO 9001: 2015: Certification Number; FM 716518

2. US DFA 510(K)

   - K162381:
     MG PRO XP© Nitrile Powder Free Examination Gloves Tested For Use with Chemotherapy Drugs
   - K152479
     MG PRO© Nitrile Powder Free Examination Gloves
   - Latex Powder Free Examination glove is in-progress

3. CE and EN TEST CERTIFICATES

SATRA EC Type-Exam Certificate

1. EN ISO 21420: 2020
2. EN ISO 374-1:2016+A1:2018
3. EN 374-2: 2019
4. EN374-4: 2019
5. EN374-5: 2016
6. EN16523-1: 2015-A1: 2018

   - Nitrile Powder Free Examination glove
     EU Type-Examination Certificate Number: 2777/14960-01/E00-00
   - Latex Powder Free Examination glove
     EU Type-Examination Certificate Number: 2777/15031-01/E00-00

4. TUV Riehland or Songkhla Medical Sciences Lab Test Reports

   - Nitrile Powder Free Examination glove
   - Latex Powder Free Examination glove
   - EN455-1, EN455-2

Certificates

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Medical Glove Co., Ltd.
288 Moo 7, T. Lam Thap,
A. Lam Thap,
Krabi
81190
Thailand

Holds Certificate Number: **MD 716521**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture and distribution of examination gloves.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-01-15
Latest Revision Date: 2020-01-15

Effective Date: 2020-01-15
Expiry Date: 2023-01-14

Page: 1 of 1

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.
Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificates

SATRA TECHNOLOGY

Issued to:

Medical Glove Co. Ltd
288 Moo 7 T.Lam Thap
A. Lam Thap
Krabi
81190
Thailand

Notified Body: 2777

SATRA customer number: P20208

EU Type-Examination Certificate

Certificate number: 2777/14960-01/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:

NBR-001

Description:

Nitrile Powder-Free Examination Glove.

Colour: Blue

Sizes:

6(S)
7(M)
8(L)
9(XL)

Classification:

EN ISO 374-1:2016+A1:2018/ Type B	Level	EN ISO 374-4:2019 Degradation %
40% Sodium Hydroxide (K)	6	-89.7
30% Hydrogen peroxide(P)	3	23.0
25% Ammonium hydroxide (O)	1	-4.3
37% Formaldehyde(T)	5	-52.0

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0298894/Issue 2/2024, CHM0299061/2024/JH/A, CHM0299061/2024/JH/B, CHM0299061/2024/EN/C, CHM0300170/2029/EN/Final, CHM0300170/2029/EN/B

Signed on behalf of SATRA: Daisy He Daisy He Jacque Glasspool

Date first issued: 24/08/2020
Date of issue: 24/08/2020

Expiry date: 24/08/2025

Page 1 of 2

SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland.

Certificates

Products

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Precisely Right.

Report No.: 242122555-01 Page 1 of 8

Client: MEDICAL GLOVE CO., LTD.

Contact Information: 288 Moo 7, T. Lam Thap, A. Lam Thap, Krabi 81190 Thailand

Identification / Model No(s): Nitrile Powder Free Examination glove

Sample Receiving date: 2020-08-28

Testing Period: 2020 08 28 to 2020 09 11

Delivery condition: *Apparent good, Samples tested as received*

Test Specification:	*Test result:*
1. EN 455-1: 2000: Requirements for freedom from holes	PASS
2. EN 455-2: 2015: Physical properties test;	
- Dimension test	PASS
- Force at break test	PASS

Other Information:

Lot No.: 200716L305

Material type: Nitrile

Manufacture: Medical glove Co., Ltd.

Country of Origin: Thailand

For and on behalf of
TÜV Rheinland Thailand Ltd.

TÜV RHEINLAND THAILAND LTD TÜV

2020-11-02 Wilawan Sriphrom / Manager

Date *Name/Position*

Test result is drawn according to the kind and extent of tests performed.
This test report relates to the above mentioned Test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

TÜV Rheinland Thailand Ltd. · Global Technology Assessment Center Bangkok (GTAC BKK) Ladkrabang Industrial Estate 123/1, Soi Chalongkung 31, Lamplatew, Ladkrabang, Bangkok 10520 Thailand
Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: info@tha.tuv.com · Web:www.tuv.com

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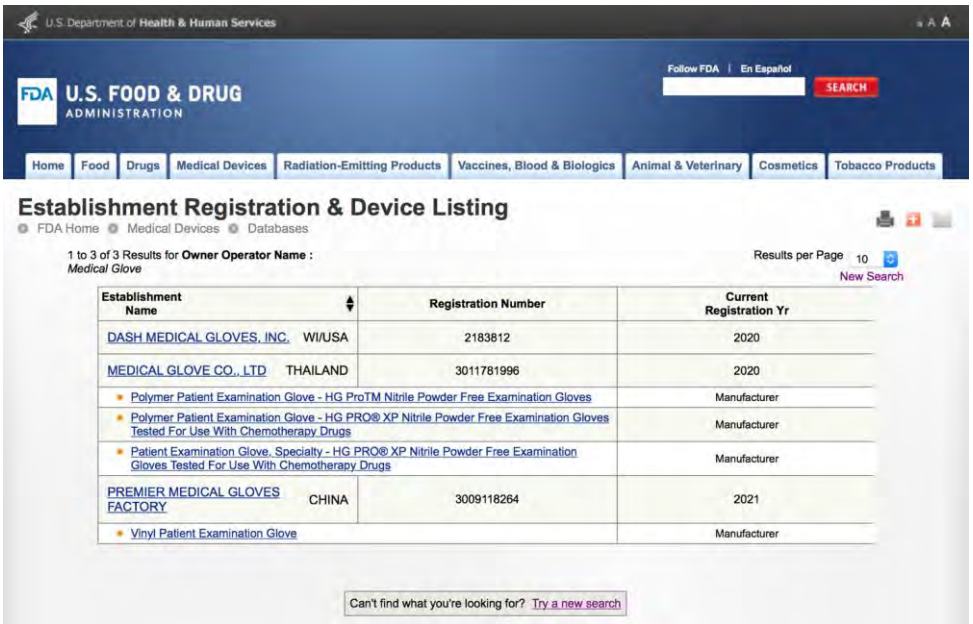

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Establishment Registration & Device Listing

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1 to 3 of 3 Results for **Owner Operator Name :** *Medical Glove*

Results per Page 10 New Search

Establishment Name	Registration Number	Current Registration Yr
DASH MEDICAL GLOVES, INC. WI/USA	2183812	2020
MEDICAL GLOVE CO., LTD THAILAND	3011781996	2020
• Polymer Patient Examination Glove - HG ProTM Nitrile Powder Free Examination Gloves		Manufacturer
• Polymer Patient Examination Glove - HG PRO® XP Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs		Manufacturer
• Patient Examination Glove, Specialty - HG PRO® XP Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs		Manufacturer
PREMIER MEDICAL GLOVES FACTORY CHINA	3009118264	2021
• Vinyl Patient Examination Glove		Manufacturer

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Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K152479
Device Name	HG Pro Nitrile Powder Free Examination Gloves
Applicant	HEALTHY GLOVE CO.,LTD 119 Kanchanavanich Road, Tambol Patong Hat Yai, TH 90230
Applicant Contact	Teoh Choh Shee
Correspondent	HEALTHY GLOVE CO.,LTD 119 Kanchanavanich Road, Tambol Patong Hat Yai, TH 90230
Correspondent Contact	Teoh Choh Shee
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	08/31/2015
Decision Date	04/04/2016
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Certificates

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

April 4, 2016

Healthy Glove Co., Ltd.
Teoh Shee
Managing Director
119 Kanchanavanich Road, Tambol Patong
Hat Yai, Songkhla 90230
THIALAND

Re: K152479
Trade/Device Name: HG PRO® Nitrile Powder Free Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 15, 2016
Received: March 7, 2016

Dear Mr. Shee:

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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

JOINT VENTURE AGREEMENT

GLOVE FACTORY JOINT VENTURE AGREEMENT

Date : October 2, 2020

Medical Glove Co., Ltd, a limited liability company with its registered office at 288, Moo 7, T Lam Thap, Amphur Lam Thap, Krabi 81190, Thailand; and **Wimax Gloves (Thailand) Co., Ltd.** and its parent company **Wimax Group Co., Ltd,** with registered office at 31/40, Krung Thep Kritha Road, T Thap Chang, Saphan Sung, Bangkok 10240 Thailand have agreed to enter into joint venture agreement to build and install 35 glove dipping lines at 2 factory sites. A new joint venture special company will be incorporated to undertake the new glove factory construction and production line installation projects.

The new glove factories and the dipping lines will be located at the following sites:

1. Lam Thap, Krabi - 15 dipping lines
2. Hatyai, Songkhla - 20 dipping lines

The total amount of capital expenditure earmarked for these new factories and dipping lines is THB [redacted]

The new factories and glove dipping lines will produce nitrile and latex examination gloves which will be sold under its own in-house brands and other OEM brands. Gloves are manufactured in accordance with ASTM and EN standards, and the company has all necessary regulatory approvals and certificates for shipment to USA, Europe and other major importing countries.

Medical Glove Co., Ltd

Signature

MR. TEOH CHOH SHEE

Managing Director

MG MEDICAL GLOVE CO.,LTD. บริษัท เมดิคอล โกลฟ จำกัด

Wimax Gloves (Thailand) Co., Ltd & Wimax Group Co., Ltd.

Signature

MISS BOONTHARIKA SARIKHAGANON

Director

Wimax Gloves (Thailand) Co., Ltd.

Certificates

Wimax Gloves

WIMAX GLOVES THAILAND

Manufacture of sanitary or hygienic appliances made of rubber Business-retail and export of all types.

☰ Menu

Wimax Gloves

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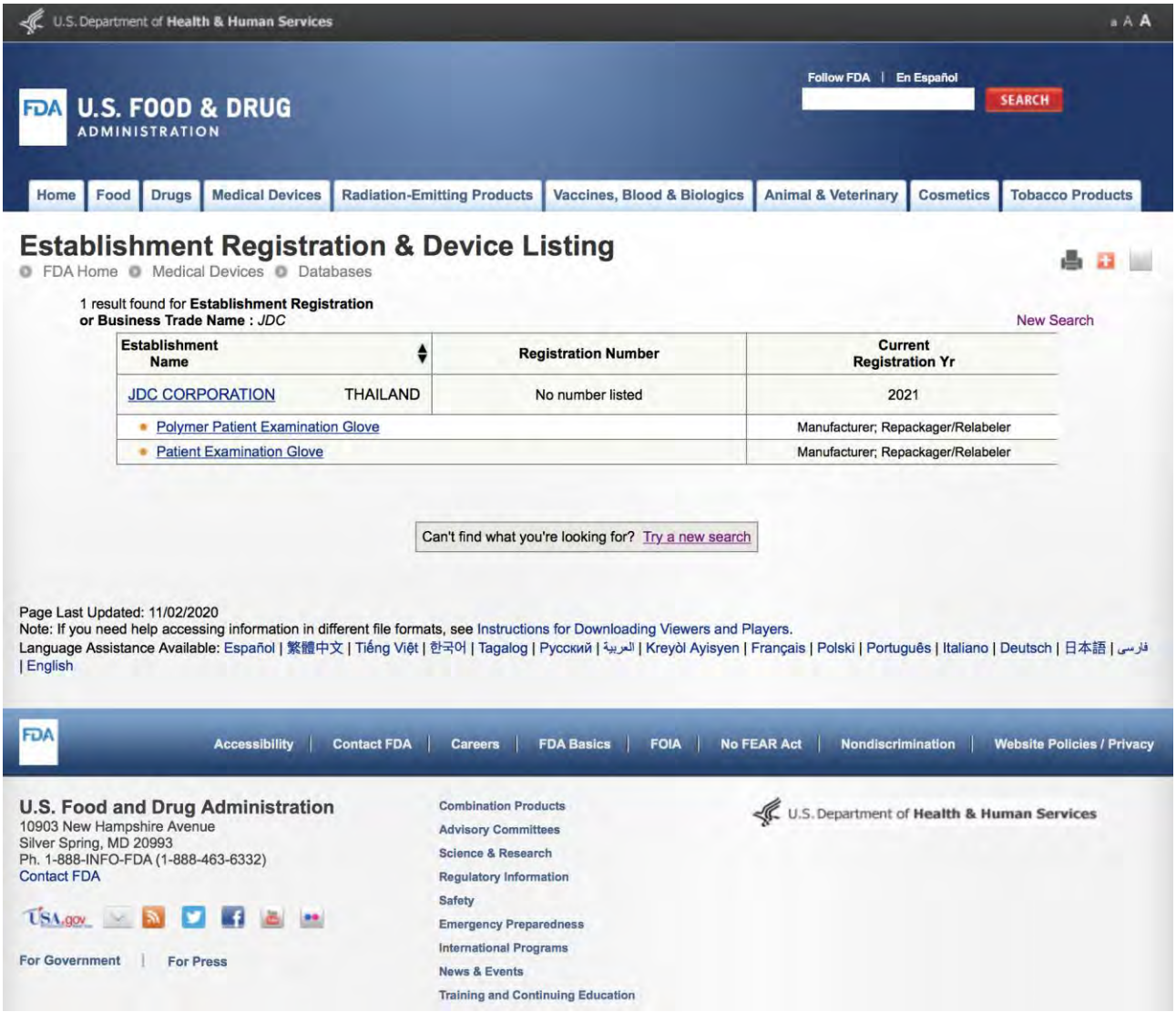

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Establishment Registration & Device Listing

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1 result found for **Establishment Registration or Business Trade Name :** *JDC*

New Search

Establishment Name		Registration Number	Current Registration Yr
JDC CORPORATION	THAILAND	No number listed	2021
• Polymer Patient Examination Glove			Manufacturer; Repackager/Relabeler
• Patient Examination Glove			Manufacturer; Repackager/Relabeler

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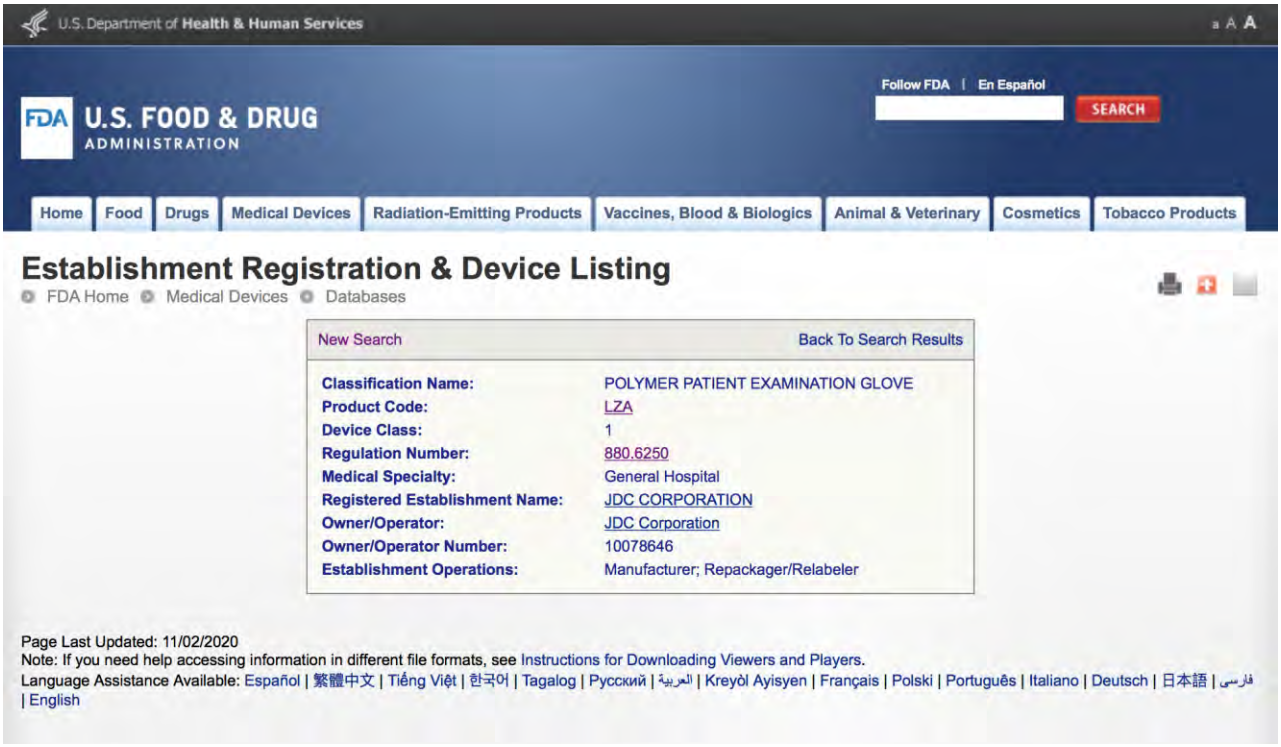

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Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	JDC CORPORATION
Owner/Operator:	JDC Corporation
Owner/Operator Number:	10078646
Establishment Operations:	Manufacturer; Repackager/Relabeler

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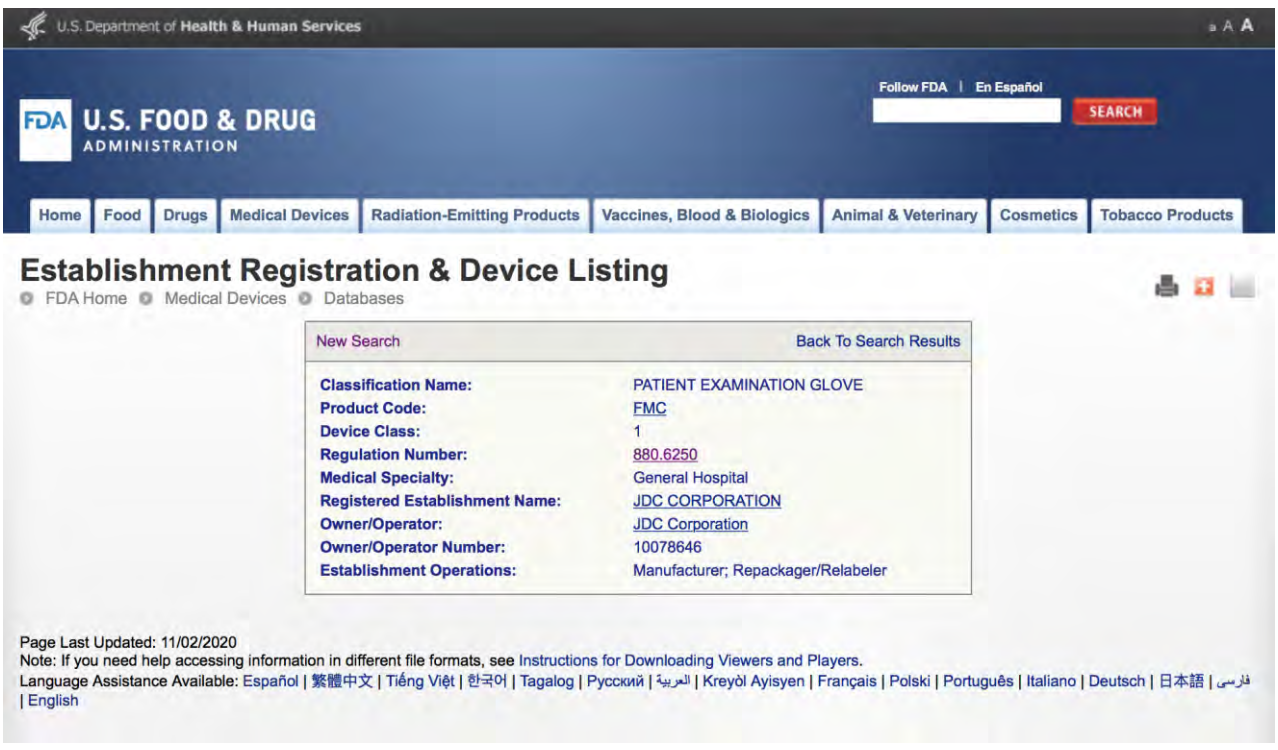

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Classification Name:	PATIENT EXAMINATION GLOVE
Product Code:	FMC
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	JDC CORPORATION
Owner/Operator:	JDC Corporation
Owner/Operator Number:	10078646
Establishment Operations:	Manufacturer; Repackager/Relabeler

Page Last Updated: 11/02/2020
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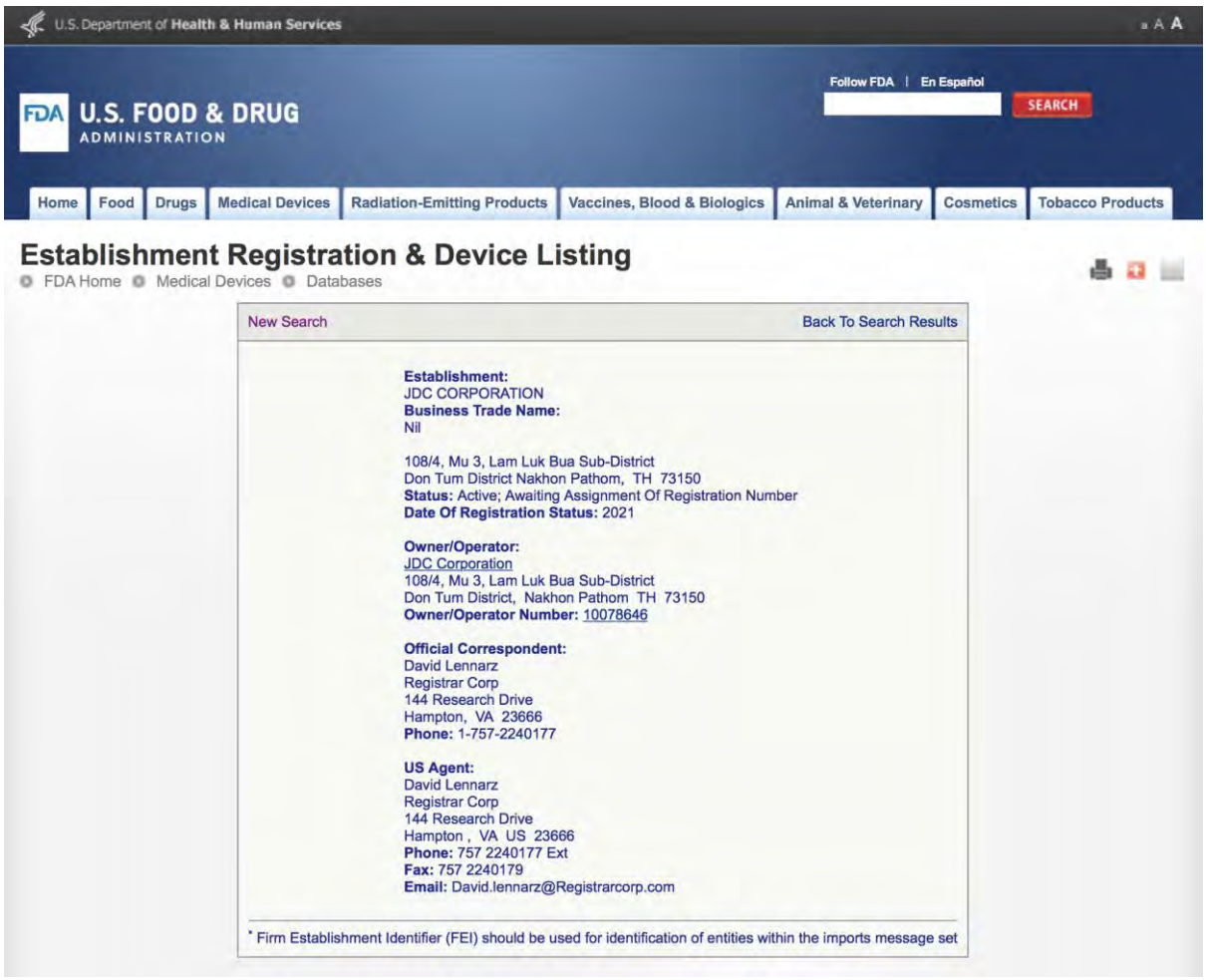
Certificates



U.S. Department of Health & Human Services

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Establishment Registration & Device Listing

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Establishment:
JDC CORPORATION
Business Trade Name:
Nil

108/4, Mu 3, Lam Luk Bua Sub-District
Don Tum District Nakhon Pathom, TH 73150
Status: Active; Awaiting Assignment Of Registration Number
Date Of Registration Status: 2021

Owner/Operator:
JDC Corporation
108/4, Mu 3, Lam Luk Bua Sub-District
Don Tum District, Nakhon Pathom TH 73150
Owner/Operator Number: 10078646

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

Certificates

2021

CERTIFICATE OF REGISTRATION

This certifies that:

JDC CORPORATION
108/4, Mu 3, Lam Luk Bua Sub-District
Don Tum District Nakhon Pathom, TH 73150

is registered with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10078646**
Device Classification Name:	**POLYMER PATIENT EXAMINATION GLOVE**
Product Code:	**LZA**
Regulation Number:	**880.6250**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated prior to issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

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David Lennarz
Executive Director
Registrar Corp
Dated: November 3, 2020