

Sufficiency Economy City .Co.Ltd

วินวิน ทาวเวอร์ ชั้น 10

อาคาร วินวิน ทาวเวอร์ ถนน รัชดาภิเษก แขวงจันทระเกษม
เขตจตุจักร กรุงเทพมหานคร 10900



SKYMED[®]



SKYMED[®]

PRODUCT

Nitrile Disposable Examination Gloves

Latex Disposable Examination Gloves

TRADE NAME : SKYMED



SKYMED[®]

Blue Nitrile Powder Free Non-Sterile



FDA
CE



EMAIL : RAHUL9A@GMAIL.COM

SKYMED[®]

Blue Nitrile Powder Free Non-Sterile



FRONT



BACK



SKYMED[®]

Blue Nitrile Powder Free Non-Sterile



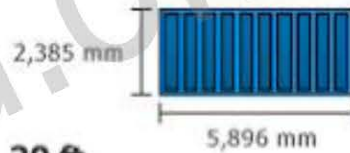
SKYMED[®]

Blue Nitrile Powder Free Non-Sterile

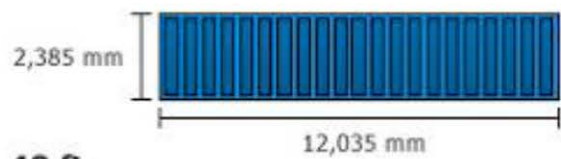


1,440 cartons /20'GP 27 CBM
3,300 cartons /40'Hc 69 CBM

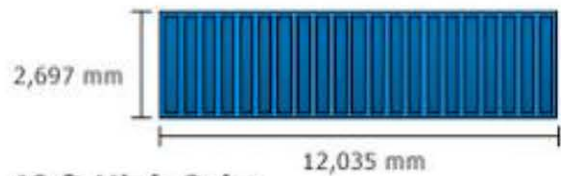
Dry Freight Container



20 ft



40 ft



40 ft High Cube

- *1 pallet (1200x800 mm) = Maximum 60 Cartons
- ~ Weight (Full Pallet) = 398 Kg.
- ~ Hight = 1,380 mm.
- ** EST Size L

EMAIL : RAHUL9A@GMAIL.COM

SKYMED[®] Non-Sterile Latex Gloves For Medical

FDA

CE



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SKYMED[®]

Non-Sterile Latex Gloves For Medical

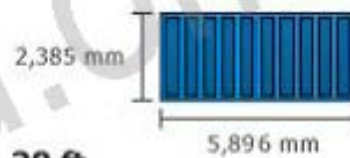


Non-Sterile Latex Gloves For Medical



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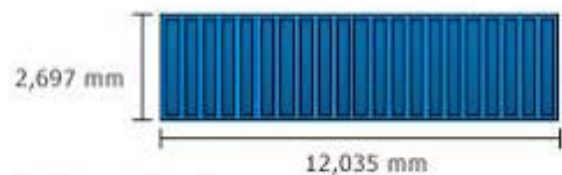
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BRAND DECLARATION

SKYMED[®]

We declare that brand SKY MED is owned by us and we have exclusive rights for this brand.



Sr.Gp.Capt.Kampee Kampeerayannon
CEO / Chairman, People's Health Promotion Project
Sufficiency Economy City Co., Ltd.
Tel : + 66 89 1155551 , + 66 86 9555599
Email : k.kampee@gmail.com

Sufficiency Economy City.,Co.Ltd

Joint Operation and manufacturing process

Healthy Gloves& Medical Gloves

Joint Operating Agreement and Manufacturing Process

SKYMED[®]

Sufficiency Economy City Co.,Ltd. & Medical Glove Co.,Ltd. & Healthy Glove Company Limited hereby certify that we agree to join operating the manufacturing process of SKYMED Gloves in order to serve the global demand.

As the mentioned in the Krabi Provincial Industry Office, Healthy Glove Co.,Ltd.have appointed Medical Glove Co.,Ltd. replaced and contract agreements offered to Medical Glove Co.,Ltd. to official manufacturing under all documents and licenses of Healthy Glove Co.,Ltd. As per enclosed documents for references be lows;



Sr.Gp.Capt.Kampee Kampeerayannon
CEO/Chairman
People,s Health Promotion Project
Sufficiency Economy City Co., Ltd.



Nirundon Thunnio
Director of Medical Glove
Co.,Ltd.



Jessada Raksrithong and;
Anothai Raksrithong,
Director of
Healthy Glove Company Limited.

DATA SHEET

Joint Operation and manufacturing process

Healthy Gloves& Medical Gloves

MATERIAL SAFETY DATA SHEET

MSDS – 02 - 01

Product: Nitrile Examination Gloves

Issue Date: 14/05/2020

Section 1: Manufacturer Identification

Name & Address	Emergency Telephone No.	Telephone No. for information
Medical Glove Co., Ltd	+6675 626500	+6675 626500
288 M. 7, T. Lam Thap, A. Lam Thap,		
Krabi 81190 Thailand		

Section 2 : Primary Material and Ingredients Information**Primary Material**

Gloves are made from synthetic-nitrile latex (Copolymer of Acrylonitrile / Butadiene / Methacrylic Acid)

Other Ingredients	CAS No.	Content(%)
Acrylonitrile-Butadiene Rubber	Proprietary	45
Zinc Oxide	1314-13-2	1.2
Sulphur	7704-34-9	1
Titanium Dioxide (White Pigment)	13463-67-7	1.7
Zinc Dibutyl Dithiocarbamate	136-23-2	0.4
Zinc Diethyl Dithiocarbamate	14324-55-1	0.2
Potassium Hydroxide	1310-58-3	2.5
Pigment	Proprietary	As per customer's requirement
Water		

All the above chemicals used are non toxic or non hazardous

Section 3 : Glove Physical Data**Dimension**

Size	X-Small	Small	Medium	Large	X-Large
Palm Width (mm)	70-79	80-89	90-99	100-109	110-119
Length (mm)	240 min.				

Single Wall Thickness

Finger	0.11 mm (min)
Palm	0.08 mm (min)



FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

510(k) Premarket Notification

1 to 2 of 2 Results
Applicant: Healthy Glove Decision Date To: 06/17/2020

Results per Page 10

Device Name	Applicant	510(K) Number	Decision Date
Hq Pro Xp Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs	HEALTHY GLOVE CO., LTD	K162381	01/31/2017
Hq Pro Nitrile Powder Free Examination Gloves	HEALTHY GLOVE CO.,LTD	K152479	04/04/2016



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-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
THAILAND

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



Healthy Gloves& Medical Gloves

Page 2 - Mr. Shee

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

Product Certificates

Sufficiency Economy City.,Co.Ltd

Joint Operation and manufacturing process

Healthy Gloves& Medical Gloves



Santé Health
Canada Canada

LNINH: 95463

Therapeutic Products Directorate
Medical Devices Bureau
Direction des produits thérapeutiques
Bureau des matériels médicaux

Medical Device Licence

Homologation d'un instrument médical

Licence Number:

95463

No d'homologation:

First Issue Date:

2015/07/17

Première date de délivrance:

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the
Medical Devices Regulations, Section 36,
for the following medical device:

La présente homologation est délivrée en vertu
de l'article 36 du Règlement sur les instruments
médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:

HG MICRO-CARE LATEX POWDER FREE EXAMINATION GLOVES

Licence Type/Type d'homologation:

Family / Famille

Manufacturer Name & Address/Nom du fabricant & adresse

HEALTHY GLOVE CO., LTD.

288 MOO 7, T.LAM THAP
KRABI
AMPHUR LAM THAP
THAILAND
81190

Carey Agnew, A/Director, Medical Devices Bureau/Directrice intérimaire, Bureau des matériels médicaux

Application Number:
Numéro de la demande:

241098

Manufacturer ID:
Identificateur du fabricant:

141011



Notified Body 0321

Issued to: **Healthy Glove Company Limited**
119 Kanchanavanich Road
Tambol Patong
Hat Yai
Songkhla 90230
Thailand

SATRA Client : P1532

EC Type-Examination Certificate

Number 8180 Issue 2

Date first issued: 13/01/2016

This is to certify that the product group reference "HG Pro PFN-002" comprising the following products:

Product Reference	Description
HG Pro PFN-002	Nitrile powder- free examination glove

Sizes: 6-10 (XS-XL)

Classification:

EN388: 2003	Level	EN374-1: 2003	Level
Abrasion resistance	0	10-13% Sodium hypochlorite	6*
Blade cut resistance	0	40% Sodium hydroxide	6
Tear resistance	0	0.1% Phenol	6
Puncture resistance	0	50% Sulphuric acid	6
		5% Ethidium bromide	6
EN374-2: 2003	Level	50% Glutaraldehyde	4
Air Leak	Pass	36% Formaldehyde	5
Water leak	Pass	1.5% Methanol	6

* Permeation rate 2µg/cm²/min**Technical reports:**

CHM0238703/1539/SPT, CHM0238703/1539/DRWM, PRC0244628/1615/SPT, PRC0244628/1615/SPT/2

has been subject to an EC Type-examination in accordance with Article 10 of the PPE Directive (89/686/EEC) and has been shown to satisfy the relevant provisions of this Directive for the complex category through:

- Testing to the following standard: **EN374-1: 2003(Excluding clause 5.3.2); EN388: 2003; EN420: 2003 + A1:2009; EN421:2010 (Radioactive Contamination Only)**
- Examination of the relevant technical documentation.

You are therefore licensed to mark the product(s) listed above in accordance with Article 13 of Directive (89/686/EEC) and any relevant amending Directives once you have drawn up an EC declaration of product conformity. Please note that:

- Full details of the certification and product are contained in the manufacturer's technical file
- This certificate is issued subject to the conditions on the reverse side of this certificate
- CE Marking of production is also reliant on current compliance with Directive 89/686/EEC Article 11
- Where a translation of this certificate exists, the English language version shall be considered as the authoritative text

Signed:

(Andrew Craggs)

Date 17/11/2016

Signed:

On behalf of SATRA

EC DECLARATION OF CONFORMITY

Name of the manufacturer : Medical Glove Co. Ltd.
 Plant of the manufacturer, address : 288 Moo 7 T.Lam Thap, A. Lam Thap Krabi 81190 Thailand.
 Product : Nitrile Powder Free Examination Gloves, GMDN: 56286
 Classification : Medical Device, Council Directive 93/42/EEC, class I
 : Personal Protective Equipment (PPE), Regulation (EU) 2016/425, category I
 Intended use : A disposable medical device intended for medical purpose and/or personal protection that is worn on the user's hands to prevent contamination and protection against low grade risks.

The undersigned hereby declares, on behalf of **Medical Glove Co., Ltd.**, that the above- referenced product, to which this declaration relates, is in conformity with the provisions of Medical Devices Directive 93/42/EEC.

Medical Glove Co., Ltd. quality management has been certified by BSI for the manufacturer of natural and synthetic latex examination gloves, and in compliance with the requirements of ISO 9001:2015 and ISO 13485:2016.

All supporting documentation is retained under the premises of the manufacturers.

Reference Standards:

- EN 455-1 : Medical glove for single use –part 1
 Requirement and testing for freedom from holes.
 EN 455-2 : Medical glove for single use –part 2
 Requirement and testing for Physical properties
 EN 455-3 : Medical glove for single use –part 3
 Requirement and testing for Biological Evaluation
 EN 455-4 : Medical glove for single use –part 4
 Requirement and testing for Shelf life determination

We further confirm that the products meets also the provision of Regulation (EU) 2016/425 for Personal (protective Equipment (PPE)). The following standards were applied to ensure conformity, EN 420:2003+A1.

Signed/Stamped by



Name : Wandee Rattanajamrong
 Position : RA/QA Manager
 Date : April 22, 2020

MEDICAL GLOVE CO.,LTD

288 Moo 7 T.Lam Thap, A. Lam Thap Krabi 81190 Thailand Cell +66 98016 6138 email info@medicalglove.net
www.medicalglove.net

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



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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.

bsi.



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

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


Holds Certificate Number:

FM 716518

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

The manufacture and distribution of examination and industrial gloves.

For and on behalf of BSI:


Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2019-12-14

Latest Revision Date: 2019-12-14

Effective Date: 2019-12-14

Expiry Date: 2022-12-13

Page: 1 of 1



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