

**MG | MEDICAL
GLOVE**
MEDICAL GLOVE CO., LTD.

iAspire
Products Ltd.

NITRILE 4 MIL POWDER FREE EXAMINATION GLOVES



🌐 www.aspireproducts.ca
✉ sales@aspireproducts.ca
☎ 519-995-5879



Your Partner in Infection Prevention, Contamination Control and Safety

Who We Are



Aspire products Ltd. is a premier trading company that started in 2020 with young entrepreneurs having more than 20 years of diverse industry experience. Our unique set of experiences, coupled with our excellent collaboration efforts, made us quickly commence business operations. Our operations are further strengthened by establishing and following internal risk management and counterparty business management systems in line with international best practices.

All the business operations that we perform are based upon the true collaboration with the right manufactures, by understanding customers' requirements and persistence in completing all orders on time. We are dedicate to providing a wide range of absolute quality and certified products for all kinds of service industries. We devote our enthusiasm and expertise to develop the most appropriate and creative products and provide close attention to each individual client. We want to leverage our experience to understand products in depth, identify areas of opportunity, and execute projects to drive growth and engagement.

FACTORY DETAILS

CORPORATE PROFILE

MEDICAL GLOVE CO., LTD.

Your most reliable partner in hand protection and safety.

Medical Glove is a established medical glove manufacturing company with manufacturing plants located in provinces of **Krabi, South of Thailand**



Powder Free Exam Glove Specifications

- ▼ Nitrile Powder Free
- ▼ Made with Nitrile Butadiene Rubber (NBR)
- ▼ Non-sterile
- ▼ Ambidextrous
- ▼ Texture at Finger Tip
- ▼ Single Use Only



General Characteristics (Specifications)

Glove Type	NITRILE
Type	Powder free, Examination gloves, Single use, Non Sterile
Color	Blue
Cuff	Beaded
Texture	Fingers
Width	S 80 (+/-10) / M 90 (+/-10) / L 110 (+/-10) / XL 120 (+/-10)
Length (mm)	S 240 (+/-10) / M 240 (+/-10) / L 240 (+/-10) / XL 240 (+/-10)
Cuff Thickness (mm)	0.06
Palm Thickness (mm)	0.08
Finger Thickness (mm)	0.10
Elongation Before Aging (%)	500
Elongation After Aging (%)	400
Tensile Strength Before Aging (Mpa)	18
Tensile Strength After Aging (Mpa)	18
Force at Break Before Aging (N)	6
Force at After Aging (N)	6
AQL	1.5
Residue Powder Content	2mg. / glove
Shelf Life (years)	3

Factory Certifications

US FDA510K	Compliant
ISO9001	Compliant
ISO14001	Compliant

Product Certifications

EU Declaration of Conformity (CE)	Compliant
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Standards of Compliance (Medical Device / PPE)

ASTM6319	Compliant
EN374-1,-5	Compliant
EN455-1,-2,-3	Compliant
ISO 21420 (Protective Glove)	Compliant



MEDICAL GLOVE CO., LTD.

NITRILE POWDER FREE EXAMINATION GLOVE POLYMER COATED SPECIFICATION

PRODUCT CHARACTERISTICS AND FEATURES

Acrylonitrile Butadiene Rubber (NBR)	
Surface Finishing	Finger surface textured with light polymer coating on the donning side.
Color	Blue
Design Feature	Ambidextrous, beaded cuff with finger textured / palm textured finishing
Shelf life	Maximum 5 years from the date of manufacturer under recommended storage conditions.
Recommended Storage Conditions	
Keep out of direct sunlight; store in a cool dry place. Keep away from sources of ozone or ignition.	

PERFORMANCE ATTRIBUTES

(Sampling Plan – ISO 2859-1: 1999: Single Inspection)

Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
Freedom from holes - Barrier	GI	1.5	ASTM D5151-06, EN455-1
Visual Defect	<ul style="list-style-type: none"> • Major Visual • Minor Visual 	GI 2.5 4.0	Industry Practice
Dimensions	S-2	4.0	ASTM D6319, EN 455-2
Physical Properties	S-2	4.0	ASTM D6319, EN 455-2
Residual Powder Content	N = 5	N/A	ASTM D6124, EN 455-3

PRODUCT PHYSICAL REQUIREMENTS

Dimensions

Physical Variable	Size	Specification Limits	Reference Standard
Length (mm)	All sizes	Min 230 Min 240	ASTM D 6319 EN 455-2
	XS	70 ± 10	
	S	80 ± 10	
	M	95 ± 10	ASTM D 6319
	L	110 ± 10	
	XL	120 ± 10	
	XXL	130 ± 10	Internal standard
Thickness (mm) *single wall	All sizes	Middle Finger Palm Cuff	Min 0.05 Min 0.05 Min 0.05
			ASTM D6319
			Internal standard

PHYSICAL STRESS-STRAIN PROPERTIES

Properties	Specification Limits		Reference Standard
	Before Aging	After Aging	
Elongation at break (%)	Min 500	Min 400	
Tensile Strength (MPa)	Min 14	Min 14	ASTM D 6319
Force at Break (N)	Median 6	Median 6	EN 455-2
Residual Powder Content	N = 5	≤ 2 mg/glove	ASTM D6124 EN 455-3

PERFORMANCE STANDARDS AND REGULATORY COMPLIANCE

ISO 9001, ISO 13485, ISO 10993-5, ISO 10993-10, FDA 510K, FDA 21 FDA 177.2600, EN 1186, ASTM F1671

Packaging & Shipment



1 Box
(Size S) 1 Box = 100 pcs
(Size M) 1 Box = 100 pcs 560 g
(Size L) 1 Box = 100 pcs 610 g

AVERAGE
M SIZE

Weight
5.8 gm

Length
240mm

100
PCS/SU

10
BOXES

S
M
L



Packaging Method View (Outer Carton)



Packaging Method View (Inner Carton)



Certificates

Request ID: 025108885

Demande n°:

Transaction ID: 076813355

Transaction n°:

Category ID: CT

Catégorie:

Province of Ontario

Province de l'Ontario

Ministry of Government Services

Ministère des Services gouvernementaux

Date Report Produced: 2020/10/08

Document produit le:

Time Report Produced: 07:58:29

Imprimé à:

Certificate of Incorporation Certificat de constitution

This is to certify that

Ceci certifie que

ASPIRE PRODUCTS LTD.

Ontario Corporation No.

Numéro matricule de la personne morale en
Ontario

002782526

is a corporation incorporated,
under the laws of the Province of Ontario.

est une société constituée aux termes
des lois de la province de l'Ontario.

These articles of incorporation
are effective on

Les présents statuts constitutifs
entrent en vigueur le

O C T O B E R 08 OCTOBRE, 2020

A handwritten signature in black ink that reads "Barbara Luckitt".

Director/Directrice

Business Corporations Act/Loi sur les sociétés par actions



MEDICAL GLOVE CO., LTD.

MEDICAL MANAGEMENT SYSTEM CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATION BY BSI

ISO 13485:2016: Certification Number, MD 716521

ISO 9001:2015: Certification Number, Mfm 716518

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

CE and EN TEST CERTIFICATES

SATRA EC Type-Exam Certificate

EN ISO 21420:2020

EN ISO 374-1:2016+A1:2018

EN 374-2: 2019

EN 374-4: 2019

EN 374-5: 2016

EN 16523-1: 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

TUV Riehland or Songkhla Medical Sciences Lab Test Reports

Nitrile Powder Free Examination glove

Latex Powder Free Examination glove

EN455-1, EN455-2



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.

**NOT FOR CIRCULATION ON SOCIAL MEDIA PLATFORMS.
FOR VERIFICATION WRITE TO inquiry@medicalglove.net**

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-01-15

Effective Date: 2020-01-15

Latest Revision 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) 2944889-93.

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, Knowhill, Milton Keynes MK5 0PP, 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.



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:	Description:
NBR-001	Nitrile Powder-Free Examination Glove.
	Colour: Blue
Sizes	Classification:
6(S)	EN ISO 374-1:2016+A1:2018/ Type B
7(M)	40% Sodium Hydroxide (K)
8(L)	30% Hydrogen peroxide(P)
9(XL)	25% Ammonium hydroxide (O)
	37% Formaldehyde(T)
	EN ISO 374-5:2016
	Protection against Bacteria and Fungi
	Protection against Viruses
	Level
	Pass
	EN ISO 374-4:2019 Degradation %
	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

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, Business Business Park, Clonlea, D15YNGP, Republic of Ireland.

Products



TÜVRheinland®
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 09 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

Manufacturer: Medical glove Co., Ltd.

Country of Origin: Thailand

For and on behalf of
TÜV Rheinland Thailand Ltd.



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 or extracted. 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) Lachirong Industrial Estate 123/1,
Soi Cherasongkran 21, Lamphithiwon, Latkrabang, Bangkok, 10520 Thailand
Tel: +66 10 2326-1333 Fax: +66 10 2326-1334-5 Email: info@tha.tuv.com Web: www.tuv.com



MEDICAL GLOVE CO., LTD

288 Moo 7 T. Lam Thap, A. Lam Thap Krabi 81190 Thailand.
Cell Phone: +66 98016 6136 Email: inquiry@medicalglove.net

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	: MG Pm Nitrile Powder Free Examination Gloves, GMDN: 56286
Classification	: Medical Device, Council Directive 93/42/EEC, class 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

Medical Glove European Authorized Representative:

RQS Wojciech Roman
ul. Zduñow 28
30-428 Cracow, Poland
Tel: +48 604 88 50 71
e-mail: ecrep@rqs.com.pl
web: www.rqs.com.pl

**NOT FOR CIRCULATION ON SOCIAL MEDIA PLATFORMS.
FOR VERIFICATION WRITE TO inquiry@medicalglove.net**

Signed/Stamped by

Name	: Wandee Rattanajamnong
Position	: RA/QA Manager
Date	: September 21, 2020

Products



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Report No.: 242122555-01

Page 1 of 8

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2. EN 455-2: 2016: Physical properties test;
 - Dimension test
 - Force at break test

PASS

PASS

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.



2020-11-02

Wilawan Sriphrom / Manager

Name/Position

Test result is drawn according to the kind and extent of tests performed.

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Tel.: +66 (0) 2326-1333 Fax: +66 (0) 2326-1334-5 Email: info@tha.tuv.com Web: www.tuv.com



Thank You

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Windsor, N9A 1B3, ON, **Canada**.
Mobile : **519-995-5879**

🌐 www.aspireproducts.ca
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Factory Address :

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