

MIDDLE WORLD[®]

Nitrile Powder Free Gloves



Latex free | Textured | Powder free | Non sterile | Ambidextrous

100 pcs S

MIDDLE WORLD® Nitrile Powder Free Gloves

MIDDLE WORLD® Glove

Nitrile Powder Free Gloves Examination

Latex free | Textured | Powder free | Non sterile | Ambidextrous



100 pcs S

CE 2777 EN 420

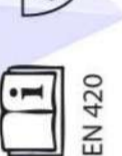


100 pcs S

MIDDLE WORLD®
Nitrile Powder Free Gloves



100 pcs S

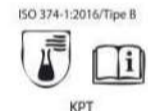


MIDDLE WORLD®
Nitrile Powder Free Gloves



MIDDLE WORLD® Glove Nitrile Powder Free Gloves

- ENG High Protection Against Microorganism And Fluids
Protection Against Certain Cytostatic And Certain Chemicals
Specially Designed For Tasks That Require High Precision
- ! Not Sterile , Ambidextrous , Do Not Expose To Sources Of Direct Light Or Ozone



- ENG EN 455-1: The legislation specifies the requirements and provides methods for the testing of medical disposable gloves to determine the absence of holes : Sampling, control level and AQL
- EN 455-2: The requirements and test methods for the physical properties of medical disposable gloves, to ensure an adequate level of protection from mutual contamination of the patient and the user.
- EN 455-3: The regulation specifies the requirements relating to the evaluation of biological safety for the medical disposable gloves and clarifies the indications on the labeling and packaging of gloves, and disclosure of information relating to the test methods used.
- EN 455-4: Indicates the requirements and test methods for establishing the validity period of the product ("shelf life determination") and indicate the deadline.
- EN 420:2003+A1:2009: Protective gloves - General requirements and test methods.
- ISO 374-1:2016/Type B



ISO 374-5:2016



VIRUS

- EN 374 - 1: Protective Gloves Against Chemicals and Micro-Organisms
- EN 374 - 2: Determination to Resistance to Penetration
- EN 374 - 3: Determination of Resistance to Permeation by Chemicals (replaced by EN 16523)
- EN 374 - 4: Determination of Resistance to Degradation by Chemicals
- EN 374 - 5: Terminology and Performance Requirements for Micro-Organism Risks



EN 420



VIRUS



KPT



9001:2016



13485:2016



9001:2016



13485:2016



9001:2016



13485:2016



9001:2016



13485:2016



9001:2016



13485:2016



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13485:2016



MIDDLE WORLD® Nitrile Powder Free Gloves

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Ref. 147769



8 423961 477698

MIDDLE WORLD[®] Glove

Nitrile Powder Free Gloves

Examination



100 pcs S

Latex free | Textured | Powder free | Non sterile | Ambidextrous



MIDDLE WORLD
Nitrile Powder Free Gloves

100 pcs S

CE 2777

EN 420

ISO 3281:2016
VIRUS

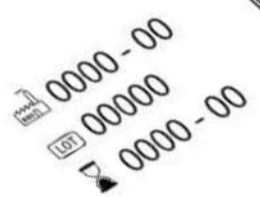
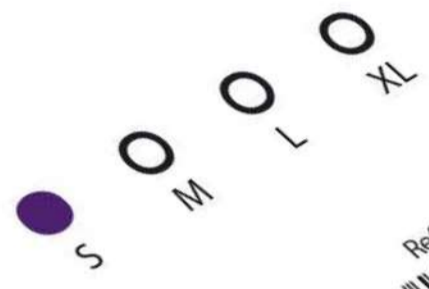
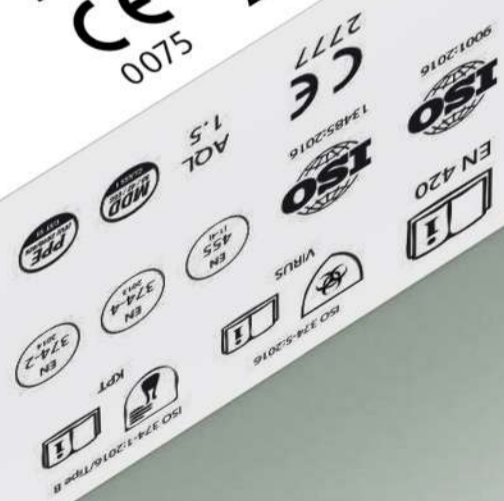
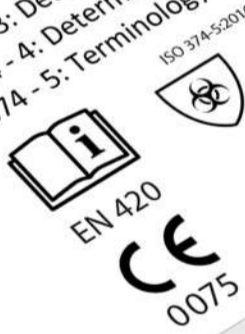
ISO 3741:2016/Type II
KPT



ENG EN 455-1: The legislation specifies the requirements and provides methods for the testing of medical disposable gloves to determine the absence of holes: Sampling, control level and AQL
 EN 455-2: The requirements and test methods for the physical properties of medical disposable gloves, to ensure an adequate level of protection from mutual contamination of the patient and the user.
 EN 455-3: The regulation specifies the requirements relating to the labeling and packaging of gloves, and disclosure of information relating to the test methods used.
 EN 455-4: Indicates the requirements and test methods for establishing the validity period of the product ("shelf life determination") and indicate the deadline.
 EN 420:2003+A1:2009. Protective gloves - General requirements and test methods.

ISO 374-1:2016/Typo B :Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound.
 Pressure — Precision methods for reverberation test rooms.
 EN ISO 374-5:2016: Protective gloves against dangerous chemicals and micro-organisms is classified in these ICS categories:
 • 01.040.13 Environment. Health protection.
 • 13.340.40 Hand and arm protection

- EN 374 - 1: Protective Gloves Against Chemicals (replaced by EN 16523)
- EN 374 - 2: Determination of Resistance to Penetration by Chemicals
- EN 374 - 3: Determination of Resistance to Degradation by Chemicals
- EN 374 - 4: Determination of Resistance to Permeation by Chemicals
- EN 374 - 5: Terminology and Performance Requirements for Micro-Organism Risks



*This box constitutes the information booklet. All gloves are for single use only.
 High protection Against Microorganism And Fluids
 Protection Against Certain Chemicals
 Specially Designed For Tasks That Require High Precision Of Direct
 Not Sterile, Ambidextrous, Do Not Expose To Sources Of Direct
 Light Or Ozone

MIDDLE WORLD
 Nitrile Powder Free Gloves
 Glove



MIDDLE WORLD[®] Glove

Nitrile Powder Free Gloves

Examination

100 pcs S

MIDDLE WORLD[®]
Nitrile Powder Free Gloves

Latex free
ASTROS

MIDDLE WORLD[®]

Nitrile Powder Free Gloves

Alta protección frente a microorganismos y fluidos.
Protección frente a ciertos citostáticos y ciertos químicos.
Especialmente diseñado para tareas que requieren alta
No estériles · Ambidextros · No exponer a fuentes de luz
de ozono.

100 pcs S

Latex free
ASTROS

Textured | Powder free | Non sterile | Ambidextrous



MIDDLE WORLD®





MIDDLE WORLD[®]

MIDDLE WORLD LTD
Company number: 13264748
27 Old Gloucester Street, London,
England, WC1N 3AX

Phone: (+44) 07895312609
(+44) 07857583355 WhatsApp

Email: info@middle.world

Website: <http://middle.world>

Social Media: middleworldltd

facebook.com/middleworldltd

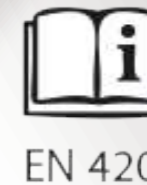




MIDDLE WORLD®

CERTIFICATE & MARKING

We have applied and are maintaining a quality management system ISO 9001:2015, ISO 13485:2016 and food safety quality management system ISO 22000:2005 for our products. At the same time, we are honored to receive the FDA 510K Certificate, Certificate from Ministry of health in Viet Nam and conformity Certificate from quatest 3 in Viet Nam





CERTIFICATION OF REGISTRATION 2021

This certifies that:

The World Investment Development Joint Stock Company

**No.164, Trieu Viet Vuong Street, Nguyen Du Ward, Hai Ba Trung District,
Ha Noi City, 100000, VIET NAM**

*Was registered with US Food and Drug Administration, Center for
Devices and Radiological Health, pursuant to the Code of Federal
Regulations 21 CFR 807, by SHT Technology Co., Ltd.*

Owner / Operator Number: 10068986
Expiration Date: Dec. 31, 2021

Device Name	Product Codes	Device Class	Listing Number
Polymer patient examination glove	LZA (510K)	I	D421204

SHT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SHT 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. 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." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SHT is not affiliated with the U.S. Food and Drug Administration.



Oct.16.2020

DATE

RYAN MA



Certificate of Compliance

Application for
Medical Device Directive (MDD) 93/42/EEC &
This is to certify that the product(s):

95 Face Mask, Medical Masks (3-Layer Medical Face Masks, 4-Layer Medical Face Masks, Surgical Disposable), Medical Gowns (Non-Surgical Isolation Gowns, Surgical Isolation Gowns), Protective Clothes (Protective Coveralls), Medical Gloves (Nitrile Gloves / Non - Powdered Gloves), N95 Respirator (Respirator, Surgical), Sanitary, Cotton Sanitary, Cotton Swabs & Medical Cotton.

Manufactured by

THE WORLD INVESTMENT DEVELOPMENT JOINT STOCK COMPANY

No. 164, Trieu Viet Vuong Street, Nguyen Du Ward, Hai Ba Trung District, Hanoi City, Vietnam

Factory 1: Section 19/8, Tu Ky town, Tu Ky district, Hai Duong province, Vietnam

Factory 2: Km410 + 500 Ho Chi Minh road, Phu Cat commune, Quoc Oai district, Hanoi, Vietnam

Factory 3: Group 2, Tan Binh quarter, Xuan Mai town, Chuong My district, Hanoi, Vietnam

Factory 4: Km 34, provincial road 379, Tan Tien commune, Van Giang district, Hung Yen province, Vietnam

Factory 5: C3 Trung Ha Industrial Park, Dan Quyen Commune, Tam Nong District, Phu Tho Province, Vietnam

Complies with the requirement of the
"MDD"

has been assessed and found in accordance with the requirements of
MDD 93/42/EEC as amended by 2007/47/EC Class I (Non-Sterile)

QCC is non-notified certification body, issue this
'compliance certificate' after audit of manufacturer product(s) & technical file(s).

This certificate applies to the tested sample only not for whole production.

It's manufacturer sole responsibility to meet all the necessary conformity
assessment activities according to **MDD 93/42/EEC & CD 76/768/EEC** and
related standards before placing them on the market & CE mark on the product(s).

Certificate No. : **CE/018915/1020**
Original Certificate Date : 13 - October - 2020
Issue Date : 13 - October - 2020
Expiry Date : 12 - October - 2021



To check this certificate status visit:
"http://uasl.uk.com/certifiedorganization.html"

Authorised Signature

For Quality Control Certification

UK Office: 1929, Chynoweth House,
Trevissome Park, Truro-TR48UN, Cornwall, UK



Quality Control Certification accredited by UASL, UK
This certificate doesn't provide the certified organisation with immunity from its legal obligations.
This certificate remains the property of QC Certification to whom it must be returned on request.



CERTIFICATE

No.: **YT 157-20**

THE WORLD INVESTMENT DEVELOPMENT JOINT STOCK COMPANY

No. 164, Trieu Viet Vuong street, Nguyen Du ward, Ha Ba Trung district, Hanoi, Vietnam

Factory 1: Section 19/8, Tu Ky town, Tu Ky district, Hai Duong province, Vietnam

Factory 2: Km 410+500 Ho Chi Minh road, Phu Cat commune, Quoc Oai district, Hanoi, Vietnam

Factory 3: Group 2, Tan Binh quarter, Xuan Mai town, Chuong My district, Hanoi, Vietnam

Factory 4: Km 34, provincial road 379, Tan Tien commune, Van Giang district, Hung Yen province, Vietnam

Factory 5: C3 Trung Ha industrial park, Thuong Nong commune, Tam Nong district, Phu Tho province, Vietnam

has been assessed and found to conform
with the requirements of the following standard:

ISO 13485:2016

Quality Management System

for the following activities:

Production and trading of The World medical masks, The World medical gloves

This certificate is valid from:

27 / 7 / 2020 to 26 / 3 / 2023

CERTIFICATION BOARD
CHAIRMAN

Prof. Dr. Nguyen Hong Son



ON BEHALF OF DIRECTOR
VICE DIRECTOR

Dr. Ngo Tat Thang



INSTITUTE FOR STANDARD AND QUALITY DEVELOPMENT STUDIES

Office: No. 52, lane 46, Lien Mac road, Lien Mac ward, Bac Tu Liem district, Ha Noi city, Vietnam

Tel. 024 2266 1111 Email: tcvn@issq.org.vn

Số: 200000004/PCBSX-PT

Tỉnh Phú Thọ, ngày 31 tháng 07 năm 2020

PHIẾU TIẾP NHẬN

Hồ sơ công bố đủ điều kiện sản xuất trang thiết bị y tế

1. Tên cơ sở công bố: CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD
2. Địa chỉ: Số 164, phố Triệu Việt Vương, Phường Nguyễn Du, Quận Hai Bà Trưng, Thành phố Hà Nội
(Sản xuất tại: CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD; Địa chỉ: Khu công nghiệp C3 Trung Hà, Xã Thượng Nông, Huyện Tam Nông, Tỉnh Phú Thọ)
3. Điện thoại: 02435625999 Fax:
4. Số văn bản đề nghị của cơ sở: 30072020 Ngày: 30/07/2020
5. Tên trang thiết bị y tế cơ sở công bố sản xuất:
Găng tay y tế
6. Thành phần hồ sơ:

1	Văn bản phân công, bổ nhiệm người phụ trách chuyên môn của cơ sở sản xuất	X
2	Bản xác nhận thời gian công tác	X
3	Văn bằng, chứng chỉ đào tạo về kỹ thuật thiết bị y tế hoặc quản lý thiết bị y tế của người phụ trách chuyên môn	X
4	Văn bản công bố đủ điều kiện sản xuất	X
5	Bản kê khai nhân sự	X
6	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng	X
7	Hồ sơ về thiết bị và quy trình sản xuất, kiểm tra chất lượng phù hợp với yêu cầu của loại trang thiết bị y tế mà cơ sở sản xuất	X
8	Hợp đồng với cơ sở đủ năng lực kiểm tra chất lượng để kiểm tra chất lượng trang thiết bị y tế mà cơ sở sản xuất	X

NGƯỜI TIẾP NHẬN HỒ SƠ

Trần Minh Khánh

admin

Số: 200001372/PCBA-HN

Thành phố Hà Nội, ngày 06 tháng 08 năm 2020

PHIẾU TIẾP NHẬN

Hồ sơ công bố tiêu chuẩn áp dụng của trang thiết bị y tế thuộc loại A

1. Tên cơ sở công bố: CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD
2. Địa chỉ: Số 164, phố Triệu Việt Vương, Phường Nguyễn Du, Quận Hai Bà Trưng, Thành phố Hà Nội
3. Số văn bản đề nghị của cơ sở: 05082020 Ngày: 06/08/2020
4. Trang thiết bị y tế thuộc loại A
Tên trang thiết bị y tế: Găng tay cao su y tế The World
Chủng loại/mã sản phẩm: Nitrile không bột
Tên cơ sở sản xuất: CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD
Địa chỉ cơ sở sản xuất: Khu công nghiệp C3 Trung Hà, xã Thượng Nông, huyện Tam Nông, tỉnh Phú Thọ, Việt Nam
Tiêu chuẩn áp dụng: 01:2020/TW
5. Thông tin về chủ sở hữu trang thiết bị y tế :
Tên chủ sở hữu: CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD
Địa chỉ chủ sở hữu: Số 164, phố Triệu Việt Vương, phường Nguyễn Du, quận Hai Bà Trưng, thành phố Hà Nội, Việt Nam
6. Thông tin về cơ sở bảo hành:
7. Thành phần hồ sơ:

1	Phụ lục chi tiết trang thiết bị y tế	X
2	Bản phân loại trang thiết bị y tế	X
3	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng còn hiệu lực tại thời điểm nộp hồ sơ.	X
4	Giấy ủy quyền của chủ sở hữu trang thiết bị y tế	X
5	Giấy xác nhận đủ điều kiện bảo hành	X
6	Tài liệu mô tả tóm tắt kỹ thuật TTBYT theo mẫu số 1 Phụ lục 8	X
7	Giấy chứng nhận hợp chuẩn hoặc Bản tiêu chuẩn mà chủ sở hữu trang thiết bị y tế công bố áp dụng	X
8	Kết quả đánh giá các thông số hóa, lý, vi sinh và các thông số khác do cơ sở đủ điều kiện theo quy định của pháp luật về đánh giá sự phù hợp cấp đối với trang thiết bị y tế sản xuất trong nước	X
9	Tài liệu hướng dẫn sử dụng của trang thiết bị y tế	X

10	Mẫu nhãn sẽ sử dụng khi lưu hành tại Việt Nam của trang thiết bị y tế	x
11	Giấy chứng nhận lưu hành tự do còn hiệu lực tại thời điểm nộp hồ sơ đối với trang thiết bị y tế nhập khẩu hoặc Phiếu tiếp nhận hồ sơ công bố đủ điều kiện sản xuất trang thiết bị y tế đối với TTBYT sản xuất trong nước	x

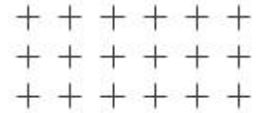
NGƯỜI TIẾP NHẬN HỒ SƠ

Nguyễn Minh Hải

Chánh Văn phòng



NITRILE GLOVES



ILLUSTRATIONS

Material	Synthetic Nitrile latex
Type	Non-Sterile Powder-Free Ambidextrous; Finger Tip Texture; Beaded Cuff; Blue and White
Quality Standards	Manufactured under ISO 9001:2015, ISO 13485:2016, FDA 510(k), CE, ASTM D6319, Quality Management System Manufactured from 100% Nitrile (Acrylonitrile-Butadiene)
Gloves Size	Extra Small, Small, Medium, Large, Extra Large marked in the check box on the shipping carton
Storage	Store in a cool and dry place, temperature is not higher
Shelf-life	3 years from the date of manufacturing.

DIMENSIONS	STANDARDS	
		ASTM D6319
Length (mm)	230 mm	220 mm (XS,S) 230 min (M, L, XL)
Width (mm)	75 ± 5 (XS) 85 ± 5 (S) 95 ± 5 (M) 105 ± 5 (L) 115 ± 5 (XL)	70 ± 10 (XS) 80 ± 10 (S) 95 ± 10 (M) 115 ± 10 (L) 120 ± 10 (XL)
Thickness-Single wall (mm)	Fingers: 0.08 mm min Palm: 0.06 mm min	Fingers: 0.05 mm min Palm: 0.05 mm min

PRODUCT	POWDER FREE NITRILE GLOVE
MATERIAL	Synthetic Nitrile latex
POWDERCONTENT	Powder content <2mg per glove
PROTEINLEVEL	Free Protein
COLOUR	Blue, White
DESIGN & FEATURES	Ambidextrous, beaded cuff, smooth or fully palm textured
PACKAGING	100pcs/box; 10 boxes/carton
BRAND	



Certificate

This is to certify that

**AN LANH INVESTMENT AND TRADING
COMPANY LIMITED**

**Lot 53,53,54 An Xa Industrial Zone, My Xa Commune, Nam Dinh City,
Nam Dinh Province, Viet Nam.**

has been found in Compliance with requirements of

Quality Management System

ISO 9001:2015

for the following scope:

**Manufacturing, Repackaging and
Trading of Gloves**

Certificate No. : 7232/QMS/1220

Issue Date : 23-December-2020

Expiry Date : 22-December-2023

To check this certificate status visit:
"<http://uasl.uk.com/certifiedorganization.html>"

Authorised Signature

International Accurate Certification

60 Mill Mead Business Centre,
Mill Mead Road, London N17 9QU, United Kingdom
www.iacert.com & info@iacert.com



This certificate remains the property of International Accurate Certification (IAC)
to whom it must be returned on request. IAC accredited by UASL (England) UK

CE CERTIFICATE



Certificate of Compliance

Application for
Medical Device Directive (MDD) 93/42/EEC

This is to certify that the product(s):
Medical Masks (3-Layer Medical Face Masks, 4-Layer Medical Face Masks)
Medical Gowns (Non-Surgical Isolation Gowns, Surgical Isolation Gowns)
Protective Clothes (Protective Coveralls) Medical Gloves (Nitrile Gloves/Non-Powdered Gloves) N95 Respirator (Respirator, Surgical)

Manufactured by

AN LANH INVESTMENT AND TRADING COMPANY LIMITED

Lot 52,53,54 An Xa Industrial Zone, My Xa Commune, Nam Dinh City,
Nam Dinh Province, Vietnam

Complies with the requirement of the
"EN 14683:2019, EN 149:2001+A1:2009; EN 14126:2019; EN 455-1/2/3/4"
has been assessed & found in accordance with the requirements of
MDD 93/42/EEC as amended by 2007/47/EC Class I (Non-Sterile)
QCC is non-notified certification body, issue this
'compliance certificate' after audit of manufacturer product(s) & technical file(s).
This certificate applies to the tested sample only not for whole production.
It's manufacturer sole responsibility to meet all the necessary conformity
assessment activities according to **MDD 93/42/EEC** and related standards
before placing them on the market & CE mark on the product(s).

CertificateNo. : CE/018599/0920 Original
Certificate Date : 24 - September -2020
IssueDate : 24 - September - 2020
ExpiryDate : 23 - September -2021



CE

Authorised Signature

For Quality Control Certification

UK Office: 1929, Chynoweth House,
Trevissome Park, Truro-TR48UN, Cornwall, UK



Quality Control Certification accredited by UASL, UK
This certificate doesn't provide the certified organization with immunity from its legal obligations.
This certificate remains the property of QCC Certification to whom it must be returned on request.



GIẤY CHỨNG NHẬN
CERTIFICATE OF REGISTRATION

Chứng nhận hệ thống quản lý chất lượng của:

This is to certify that the Quality Management System of:

CÔNG TY TNHH ĐẦU TƯ VÀ THƯƠNG MẠI AN LÀNH
AN LANH INVESTMENT AND TRADING COMPANY LIMITED

Địa chỉ & Nhà máy: Lô 52, 53, 54 đường N3 Cụm công nghiệp An Xá,
Phường Mỹ Xá, Thành phố Nam Định, Tỉnh Nam Định, Việt Nam
Address & Factory: Lot 52, 53, 54, N3 Street, An Xa Industrial Zone, My Xa Ward,
Nam Dinh City, Nam Dinh Province

Đã được đánh giá và xác nhận phù hợp với các yêu cầu của tiêu chuẩn:

Has been assessed and found to conform with the requirements of the following standard:

ISO 13485:2016

Cho lĩnh vực/ for the following activities:

Sản xuất, san lã, đóng gói, găng tay y tế

Manufacturing, subdivision, packaging of Medical Gloves

Số chứng nhận/ Certificate No: W1288M

Ngày ban hành/ Issue date: 25/12/2020

Ngày hết hạn/ Expiry date: 24/12/2023

(Hiệu lực của giấy chứng nhận các năm tiếp theo sẽ được thể hiện kèm theo quyết định duy trì chứng nhận sau mỗi lần đánh giá giám sát)



DECLARATION OF CONFORMITY



An Lanh Investment And Trading Company Limited
Lot 52,53,54, N3 Street, An Xa Industrial Zone,
My Xa Ward, Nam Dinh City, Nam Dinh
Province, Vietnam
Phone: 0936191389
Email: anlanhgauze.com
28.Dec.2020

Declaration of Conformity

An Lanh Investment and Trading Company Limited

Here by declares that our product named: Nitrile Examination Gloves – Powder Free
It is in accordance with the Regulation (EU) No 1065/2010 of the European Parliament and of the
Council and national standards in some cases, in conformance with the harmonized
standards conversion.

The object of the declaration described in point 4 is in conformity with the relevant Union
harmonization legislation: EN ISO 374-5:2016, EN 455-1:2020, EN 455-2:2015, EN 455-
3:2015

Material used in manufacturing are industrial origin and no restricted additives are
intentionally introduced in the production process.
Product use intentionally does not harmful.

In addition, the compliance is understood to be subject to the conformity with the conditions
of storage, handling and use, taking into account the specific characteristics of the material
or article, and the conditions such as prescribed by professional practices or codes.

In the event of a change in the packaged product, its composition or its intended use, as well
as in the event of a change in the conditions for using the material or the article, the person
for whom this declaration is intended must ensure the compatibility packaging / content for
which he/she then accepts responsibility.

**This declaration of compliance is based on the following (tick the appropriate boxes, if
concerned):**

Declaration(s) by suppliers of product / raw materials (components of the material aimed
by the present declaration).

This declaration of compliance is valid from 4th of Sep 2020. It should be renewed whenever
compliance to the above is no longer ensured (renewal of tests, change of material, change
of technology or evolution of regulation).

With kind regards

For and in the name of An Lanh



TỔNG GIÁM ĐỐC
NGUYỄN CHÍ DŨNG

Certificate of Registration

This is to Certify that
the technical documentation for the products of

ANLANH INVESTMENT AND TRADING LIMITED CO., LTD

LOT 52, 53, 54 - N3 STREET, AN XA INDUSTRIAL CLUSTER, MY XA COMMUNE,
NAM DINH CITY, NAM DINH PROVINCE, VIETNAM

The Technical Document maintained by the organization has been reviewed and found
to comply with the requirements Medical Device Directive (93/42/EEC) for the
following Products:

**GAUZE SPONGES, LAPAROTOMY SPONGES, NON-WOVEN GAUZE,
ROUND GENERAL SPONGES, ROUND OBSTETRIC GAUZE, TRIANGULAR
OBSTETRIC SPONGES, MECHE SPONGES, GAUZE ARTIFICIAL KIDNEY,
SURGICAL GAUZE PACKAGE, ABSORBENT GAUZE, ROLLER GAUZE,
INJURE COVERING COTTON WOOL GAUZE, ABSORBENT MEDICAL
COTTON, PLASTIC SHEET, VIRUS & INFECTIOUS DISEASE PREVENTION
KIT/ SURGEON SUIT KIT, MEDICAL CAMERA BAG, SURGICAL CAP,
MEDICAL MASK.**

(Annexure attached for details)

This certificate of compliance is based on the Technical File of the above mentioned product.

Technical Report and Documentation are at the Organization's Disposal.

This is to certify that the Product is in conformity with all revision of Council Directive 93/42/EEC
referred to as MMD. This certificate does not imply assessment of the series-production of the
product and does not permit the use of AQC Middle East FZE mark of conformity.

The manufacturer is responsible to perform all necessary activities as required by Directive before
placing the **CE** mark on the product(s).

Certificate No.	: 20ICEB44	Issuance Date	: 28/02/2020
Initial Registration Date	: 28/02/2020		
Date of Expiry *	: 27/02/2023		
1st Surve. Due	: 28/01/2021	2nd Surve. Due	: 28/01/2022



Director

AQC MIDDLE EAST FZE.



Head Office: E1-1401 E Amber Gem Tower, Sheikh Khalifa Bin Zayed Road, 2, Ajman, UAE. e-mail: info@aqcworld.com.

*Validity of the Certificate is subject to successful completion of surveillance audits on or before of due date. In case surveillance audit is not allowed to be



AQC MIDDLE EAST FZE

(An ISO Certification Body accredited by IAS)

REGISTRATION SCHEDULE

ANNEXURE - 1

COMPANY'S NAME: - ANLANH INVESTMENT AND TRADING LIMITED CO., LTD

PRODUCT NAME	TYPE
GAUZE SPONGES	Gauze sponges (sterile or non-sterile) (5cm-50cm) x (5cm-50cm) x (1 ply-24 ply)
LAPAROTOMY SPONGES	Laparotomy sponges (sterile or non-sterile) (8cm-80cm) x (8cm-80cm) x (1 ply-24 ply)
NON-WOVEN GAUZE	Non-woven gauze (sterile or non-sterile) (5cm-50cm) x (5cm-50cm) x (1 ply-24 ply)
ROUND GENERAL SPONGES	Round general sponges (sterile or non-sterile) (Fi 20-Fi 50) x (1 ply-5 ply)
ROUND OBSTETRIC GAUZE	Round obstetric gauze (sterile or non-sterile) (Fi 20-Fi 50) x (1 ply-2 ply)
TRIANGULAR OBSTETRIC SPONGES	Triangular obstetric sponges (sterile or non-sterile) (5cm-7cm) x (5cm-7cm) x (5cm-7cm)
MECHE SPONGES	Meches sponges (sterile or non-sterile) (1cm-150cm) x (1cm-150cm) x (2 ply-10 ply)
GAUZE ARTIFICIAL KIDNEY	Gauze artificial kidney (sterile or non-sterile) 3.5cm x 4.5cm x (40 ply-80 ply)
ABSORBENT GAUZE	Absorbent gauze (sterile or non-sterile) (0.75m-1.6m) x (20m-2000m)
SURGICAL GAUZE PACKAGE	Package for cesarean section, Package for a bandage change, Package for abdominal wash, Package for wound bandage, Package for major surgery, Package for middle surgery, Package for minor surgery, gauze burns package, FAV injection kit, Obstetric surgery package, catheterization kit, Drape Surgical Towel (sterile / non-sterile)
ROLLER GAUZE	Roller gauze (sterile or non-sterile) (0.025m - 0.2m) x (1m - 10m)
INJURE COVERING COTTON WOOL GAUZE	Injure covering cotton wool gauze (sterile or non-sterile) (4cm - 20cm) x (4cm - 20cm)
ABSORBENT MEDICAL COTTON	Absorbent medical cotton (sterile or non-sterile) 5g - 1kg, (1cm -10cm) x (1cm - 10cm)
PLASTIC SHEET	Nylon sheet (sterile or non-sterile) (50cm -300cm) x (50cm -300cm)
VIRUS & INFECTIOUS DISEASE PREVENTION KIT/ SURGEON SUIT KIT	(sterile or non-sterile) set include: -Surgical clothes -Surgical pants -Disposable surgical shoes -Face mask -Surgical nurse cap -Gloves -Goggles



Corporate Office: E1-1401 E Amber Gem Tower, Sheikh Khalifa Bin Zayed Road, 2, Ajman, UAE.

e-mail: info@aqcworld.com, website: www.aqcworld.com

Branch Office : 403, Mabhuban, Building No. 55, Nehru Place, New Delhi-110019, India

CE CERTIFICATE



AQC MIDDLE EAST FZE

(An ISO Certification Body accredited by IAS)

PRODUCT NAME	TYPE
MEDICAL CAMERA BAG	Camera bag (sterile or non-sterile) Nylon pipe and nylon bag
SURGICAL CAP	(sterile or non-sterile) 3.5g - 4g/ unit
MEDICAL MASK	(sterile or non-sterile) 2 ply, 3 ply, 4 ply.

Directive: Medical Device Directive (93/42/EEC)

SCOPE: - GAUZE SPONGES, LAPAROTOMY SPONGES, NON-WOVEN GAUZE, ROUND GENERAL SPONGES, ROUND OBSTETRIC GAUZE, TRIANGULAR OBSTETRIC SPONGES, MECHE SPONGES, GAUZE ARTIFICIAL KIDNEY, SURGICAL GAUZE PACKAGE, ABSORBENT GAUZE, ROLLER GAUZE, INJURE COVERING COTTON WOOL GAUZE, ABSORBENT MEDICAL COTTON, PLASTIC SHEET, VIRUS & INFECTIOUS DISEASE PREVENTION KIT/ SURGEON SUIT KIT, MEDICAL CAMERA BAG, SURGICAL CAP, MEDICAL MASK.



REGISTRATION PERIOD: - 28.02.2020 to 27.02.2023

CERTIFICATE NO: - 20ICEB44

*Subject to Successful completion of Surveillance Audits On:-

1st Surve. Due : 28/01/2021

2nd Surve. Due : 28/01/2022

Director

Corporate Office: E1-1401 E Amber Gem Tower, Sheikh Khalifa Bin Zayed Road, 2, Ajman, UAE.

e-mail: info@aqcworld.com, website: www.aqcworld.com

Branch Office : 403, Mahubun, Building No. 55, Nehru Place, New Delhi-110019, India

Test Report No. 7191248919-EEC20-WBH
dated 12 Dec 2020



Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by
AN LANH INVESTMENT AND TRADING COMPANY LIMITED on 16 Nov 2020.

Add value.
Inspire trust.

TESTED FOR:

AN LANH INVESTMENT AND TRADING COMPANY LIMITED
Lot 52,53,54 An Xa Industrial Zone,
My Xa Commune, Nam Dinh City,
Nam Dinh Province, Vietnam

TEST DATE:

18 Nov 2020 to 12 Dec 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Nitrile Examination Gloves- Powder Free	AN-Gloves	XL	Blue	201220	11/2023	494	AN LANH INVESTMENT AND TRADING COMPANY LIMITED

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

- EN 455-1:2020 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



Laboratory:
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1 Science Park Drive, #02-01
Singapore 118221
TUV[®]

Test Report No. 7191248919-EEC20-WBH
dated 12 Dec 2020



RESULTS:

Sample: Nitrile Examination Gloves- Powder Free, AN-Gloves, Blue, Size XL

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	2	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	a) Length (mm)	≥ 240	13	262	Passed
	b) Width (mm)	For Size XL: ≥ 110	13	112	Passed
5	a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	6.5	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	6.8	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Comply	Passed

Test Report No. 7191248919-EEC20-WBH
dated 12 Dec 2020



RESULTS (cont'd):

Sample: Nitrile Examination Gloves- Powder Free, AN-Gloves, Blue, Size XL

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is talcum powder-free glove, based on client's declaration letter	Passed
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.38 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove	NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex; The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
Inferred results			Passed

Test Report No. 7191248919-EEC20-WBH
dated 12 Dec 2020



REMARKS:

1. Labelling requirements are assessed based on the submitted packaging artwork by client.
2. NA: Not applicable for the submitted sample.


Yeo Poh Kwang
Associate Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo : Nitrile Examination Gloves- Powder Free, AN-Gloves, Blue, Size XL

Test Report No. 7191248919-EEC20-WBH
dated 12 Dec 2020



Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.
6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 01 September 2020



TUV Test report En 374-5, EN 374-2 & EN420

Test Report No. 7191248949-EEC20/01-LDY
dated 15 Dec 2020



PSB Singapore

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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by AN LANH INVESTMENT AND TRADING COMPANY LIMITED on 16 Nov 2020.

TESTED FOR:

AN LANH INVESTMENT AND TRADING COMPANY LIMITED
Lot 52.53.54 An Xa Industrial Zone,
My Xa Commune, Nam Dinh City,
Nam Dinh Province, Vietnam

TEST DATE:

19 Nov 2020 to 09 Dec 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Nitrile Examination Gloves - Powder Free	AN-Gloves	M	Blue	021120	11/2023	497	AN LANH INVESTMENT AND TRADING COMPANY LIMITED



Laboratory:
TUV SUD PSB Pte. Ltd.
No 1 Science Park Drive
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Co. Reg : 19900967R

Regional Head Office:
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1 Science Park Drive, #02-01
Singapore 118221
TUV®

TUV Test report En 374-5, EN 374-2 & EN420

Test Report No. 7191248949-EEC20/01-LDY
dated 15 Dec 2020



METHOD OF TEST:

The tests were conducted in accordance with the following test standards:

BS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks

- Clause 5.1 General requirements
(Test method described in EN 420:2003+A1:2009 Protective gloves – General requirements and test methods)
- Clause 5.2 Penetration
(Test method described in EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration)
- Clause 5.3 Protection against viruses
(Test method described in ISO 16604:2004, Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne Pathogens – Test method using Phi-X 174 Bacteriophage, Method B)

RESULTS:

Table 1: Results for tests according to BS EN ISO 374-5:2016 Clause 5.1-5.3

Clause	Tests	Specification	Results	Inferred Result
5.1	General Requirement	Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.	Refer to Table 2 for results of EN 420, Clause 4 and Clause 5 for applicable tests. The submitted glove and packaging not tested to EN 420 Clause 7 Marking and information as requested by client.	Passed Not tested
5.2	Penetration	Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3. 7.2 Air leak test 7.3 Water leak test	No leakage for both tests	Passed
5.3	Protection against viruses	Shall exhibit no detectable transfer (<1 PFU/ml) of the Phi-X174 bacteriophage in the assay titre	Refer to 7191248902-CHM20-02-RC for detailed results.	Passed

TUV Test report En 374-5, EN 374-2 & EN420

Test Report No. 7191248949-EEC20/01-LDY
dated 15 Dec 2020



RESULTS (cont'd):

Sample: Nitrile Examination Gloves Powder Free , AN-Gloves, Blue, Size M

Table 2: Results for EN 420:2003+A1:2009

Test	EN 420:2003+A1:2009 Requirements		Results	Inferred Results
I. Determination of pH Value, pH value	> 3.5 and < 9.5		7.7	Passed
II. Sizing, minimum length of glove (mm)	Size	Minimum length of glove (mm)	250	Passed
	M (8)	240		
III. Dexterity, level of performance	Level of performance	Smallest pin diameter fulfilling test conditions (mm)	5	See remark 1
	1	11		
	2	9.5		
	3	8		
	4	6.5		
	5	5		

REMARKS:

1. A glove should allow as much dexterity as possible given its purpose. Four gloves were tested and smallest performance level was reported.
2. For Clause 5.2 Penetration, the test sample will be four gloves of each size, with an overall minimum of 4 gloves per performed test (Air leak test and Water leak test). If one sample fails the penetration test, the test shall be reported as having failed.


Lee Dai Yi
Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo: Nitrile Examination Gloves Powder Free , AN-Gloves, Blue, Size M

TUV Test report En 374-5, EN 374-2 & EN420

Test Report No. 7191248949-EEC20/01-LDY
dated 15 Dec 2020



Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TUV SUD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TUV SUD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TUV SUD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
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6. The tests carried out by TUV SUD PSB and this report are subject to TUV SUD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TUV SUD Group.

Effective 01 September 2020



TEST ASTM D6319

Test Report No. 7191249291-EEC20/03-WBH
dated 04 Dec 2020



PSB Singapore

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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by AN LANH INVESTMENT AND TRADING COMPANY LIMITED on 16 Nov 2020.

TESTED FOR:

AN LANH INVESTMENT AND TRADING COMPANY LIMITED
Lot 52.53.54 An Xa Industrial Zone,
My Xa Commune, Nam Dinh City,
Nam Dinh Province, Vietnam

TEST DATE:

18 Nov 2020 to 03 Dec 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Nitrile Examination Gloves - Powder Free	AN-Gloves	M	Blue	021120	02/10/2023	500	AN LANH INVESTMENT AND TRADING COMPANY LIMITED

METHOD OF TEST:

ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application

- Clauses 6.1.4 & 7.5 Physical Requirements Test – Die C, accelerated aging conducted according to Clause 7.5.2.1: temperature of 70±2°C for 166±2h (Cross-reference to Test Method D412 and D573)



Laboratory:
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1 Science Park Drive, #02-01
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TUV®

TEST ASTM D6319

Test Report No. 7191249291-EEC20/03-WBH
dated 04 Dec 2020



RESULTS:

Sample: Nitrile Examination Gloves Powder Free, AN-Gloves, Blue, Size M

Table 1: Results for Physical Requirements Test – before accelerated aging

Clause	Tests	Requirements	Results			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.4 7.5	Tensile strength (MPa)	≥ 14	21	31	40	1	13	0	Passed
	Ultimate elongation (%)	≥ 500	512	535	556				

Table 2: Results for Physical Requirements Test – after accelerated aging

Clause	Tests	Requirements	Results			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.4 7.5	Tensile strength (MPa)	≥ 14	17	28	40	1	13	0	Passed
	Ultimate elongation (%)	≥ 400	480	518	556				


Yeo Poh Kwang
Associate Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

TEST ASTM D6319

Test Report No. 7191249291-EEC20/03-WBH
dated 04 Dec 2020



APPENDIX:



Photo 1: Nitrile Examination Gloves Powder Free , AN-Gloves , Blue, Size M

TEST REPORT



BỘ Y TẾ
VIỆN KIỂM NGHIỆM AN TOÀN VỆ SINH THỰC PHẨM QUỐC GIA
NATIONAL INSTITUTE FOR FOOD CONTROL (NIFC)

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VP2/Rep. Office 1: Phòng A102, Công B Công Cầu Lát, số 12950 Nguyễn Thị Đình, P. Cầu Lát, Q2, TP. HCM, Việt Nam
VP2/Rep. Office 2: Số 1 Ngõ Quyết, P. Đồng Hòa 1, Q. Hải An, TP. Hải Phòng, Việt Nam
Hotline: 19001061 Email: kmn@nifc.gov.vn Website: http://www.nifc.gov.vn

Số: 38532/PKN-VKNQG

PHIẾU KẾT QUẢ KIỂM NGHIỆM
TEST REPORT

1. Tên mẫu: Găng tay y tế. Chủng loại: Nitrile
2. Mã số mẫu: 122010761/DV.1
3. Mô tả mẫu: Mẩu đựng trong túi nilon, 100 cái/túi. Thông tin mẫu viết tay dán trên túi - Số lượng: 1
NSX - HSD: Không có; Không có mẫu lưu
4. Số lượng mẫu: 01 mẫu
5. Thời gian lưu mẫu: Không có
6. Ngày nhận mẫu: 10/12/2020
7. Thời gian thử nghiệm: 10/12/2020 - 18/12/2020
8. Nơi gửi mẫu: CÔNG TY TNHH ĐẦU TƯ VÀ TM AN LÀNH
Địa chỉ: Lô 52,53,54 đường N3 Cụm CN An Xá, Phường Mỹ Xá,
TP Nam Định, Tỉnh Nam Định, Việt Nam
9. Kết quả thử nghiệm: Các chỉ tiêu Hóa lý

STT	Tên chỉ tiêu	Đơn vị	Phương pháp thử	Kết quả	
9.1	Kích thước vật lý	Rộng	mm	TCVN 6343-1:2007	91
		Dài			238
		Độ dày			0,06
9.2	Lực kéo đứt trước khi già hóa nhanh	N	TCVN 6343-1:2007	7,25	
	Lực kéo đứt sau khi già hóa nhanh			7,10	
	Độ giãn dài khi đứt trước khi già hóa nhanh	%	TCVN 6343-1:2007	520	
	Độ giãn dài khi đứt sau khi già hóa nhanh			415	
9.3	Độ kín nước	-	TCVN 6343-1:2007	Đạt	

Hà Nội, ngày 18 tháng 12 năm 2020

TUQ.VIỆN TRƯỞNG



TRƯỞNG KHOA
ĐẢM BẢO CHẤT LƯỢNG
TS. Lê Thị Phương Thảo

1. Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu thử nghiệm/ This report is only valid for the above sample
2. Không được trích dẫn một phần hoặc toàn bộ nội dung của báo cáo này mà không có sự đồng ý bằng văn bản của Viện Kiểm Nghiệm ATYSETPQG/ This report shall not be reproduced partly without the written approval of NIFC.
3. Thông tin về mẫu và khách hàng được ghi theo yêu cầu của nơi gửi mẫu/ Information of sample and customer is written as customer's request
4. (*) Phương pháp được công nhận phù hợp theo yêu cầu của ISO/IEC 17025/ Method is accredited in accordance with ISO/IEC 17025
5. Không nhận khiếu nại trong trường hợp không có mẫu lưu hoặc hết thời hạn lưu mẫu theo quy định/ Complaints shall not be received in case the storage sample is

— Detail information submitted to Satra to get CE2777 —
is confidential

PPE Technical File

for

**Powder-free Blue Nitrile Gloves
(For Minimal Risk Only)**

(PPE/PFN-B-MR/002)

- Detail information submitted to Satra to get CE277 is confidential

Technical File: PPE/PFN-B-MR/002
Section: Table of Contents

Effective Date: 29 Jul. 2011
Page 1 of 1

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2.0	Basic Health and Safety Requirements	002
3.0	Manufacturing Process	000
4.0	Quality Control System	000
5.0	Control and Test Facilities	000
6.0	Product Testing	000
7.0	List of pictograms to be used on packages	001
8.0	List of applicable standards	001
9.0	EC Declaration of Conformity	000



Establishment Registration & Device Listing



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[Databases](#)

1 result found for Owner Operator Number :
10068986

[New Search](#)

Establishment Name	Registration Number	Current Registration Yr
THE WORLD INVESTMENT DEVELOPMENT JOINT STOCK COMPANY VIETNAM	3016739110	2021
<ul style="list-style-type: none"> Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per lie Guidance - THE WORLD INVESTMENT DEVELOPMENT JOINT STOCK COMPANY Respirator, Surgical - THE WORLD INVESTMENT DEVELOPMENT JOINT STOCK COMPANY Radiographic Protective Glove - Protection Gloves , Medical Glove Polymer Patient Examination Glove - Protection Gloves , Medical Glove 		Contract Manufacturer; Contract Sterilizer; Foreign Exporter; Manufacturer; Remanufacturer; Repackager/Relabeler Contract Manufacturer; Contract Sterilizer; Foreign Exporter; Manufacturer; Remanufacturer; Repackager/Relabeler Contract Manufacturer; Contract Sterilizer; Foreign Exporter; Manufacturer; Remanufacturer; Repackager/Relabeler; Foreign Private Label Distributor Contract Manufacturer; Contract Sterilizer; Foreign Exporter; Manufacturer; Remanufacturer; Repackager/Relabeler

Establishment Registration & Device Listing

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[Back To Search Results](#)

Establishment:

THE WORLD INVESTMENT DEVELOPMENT JOINT STOCK COMPANY

No.164, Trieu Viet Vuong Street, Nguyen Du Ward

Hai Ba Trung District

HA NOI , VN 100000

Registration Number: 3016739110

FEI Number*: 3016739110

Status: Active

Date Of Registration Status: 2021

Owner/Operator:

[The World Investment Development Joint Stock Company](#)

NO.164, Trieu Viet Vuong Street, Nguyen

Hai Ba Trung District

Ha Noi, VN 100000

Owner/Operator Number: [10068986](#)

Official Correspondent:

Thuy T Quach

NO.164, Trieu Viet Vuong Street, Nguyen

Hai Ba Trung District

Ha Noi, VN 100000

Phone: 84-91-3976795

US Agent:

Wilson Cheung

21 Farmstead Rd

Short Hills , NJ US 07078

Phone: 716 9655112 Ext

Email: Wilson.Cheung.FDA@Gmail.Com

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

THE WORLD INVESTMENT DEVELOPMENT JOIN STOCK COMPANY

NO 164 TRIEU VIET VUONG –NGUYEN DU WARD –HAI BA TRUNG DIST- HA NOI- VIET NAM

The following sample was submitted and identified on behalf of the client as below:

SGS Job No. : VNHL2008016565HG
Sample Description : NITRILE EXAMINATION MEDICAL GLOVE – POWDER FREE
Color : “XANH”
Characteristic : “CAO SU NHAN TAO / NITRILE”
Country of Origin : VIETNAM
Country of Destination : USA, EU, ASIA
Item/ Style# : 1
Date of Production : 07/2020
Manufacturer : THE WORLD INVESTMENT DEVELOPMENT JOIN STOCK COMPANY
End Users : ADULTS
Sample Receiving Date : AUGUST 21, 2020
Final confirmed Date : AUGUST 21, 2020
Testing Period : AUGUST 21, 2020 TO OCTOBER 09, 2020
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Results : PLEASE REFER TO NEXT PAGE(S).

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TEST	PASS	FAIL	REMARK
FREEDOM FROM HOLES	X		
POWDER CONTENT	X		
DIMENSIONS	X		
PHYSICAL PROPERTIES	X		

Signed for and on behalf of

SGS Vietnam LTD



Ung Thanh Van
Hardline Lab Manager

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Test results

Sample Description: 1. NITRILE EXAMINATION MEDICAL GLOVE – POWDER FREE

1. FREEDOM FROM HOLES

ASTM D5151-06 (Reapproved 2015)

Sample Size: 200pcs
 Number of non-confirming gloves: 07pcs
 Acceptable Number of non-confirming gloves: 10pcs

Note: Sampling was carried out as per ISO 2589-1 AQL of 2.5, General inspection level 1 and sample code letter L.

2. MEDICAL GLOVES FOR SINGLE USE – POWDER CONTENT

ASTM D6124-06 (Reapproved 2017)

POWDER CONTENT PER GLOVE 0.7 mg/kg Max: 2.0 mg/kg

Note: Above requirements given as per ASTM D6319-19 (Clause 6).

3. DIMENSIONS

ASTM D 3767-03 (Reapproved 2014)

	Large		Thickness (mm)	
	Length	Width	Finger	Palm
Specimen -1	242	105	0.08	0.07
Specimen -2	241	107	0.09	0.06
Specimen -3	241	107	0.09	0.07
Specimen -4	243	106	0.09	0.06
Specimen -5	241	108	0.08	0.07
Specimen -6	240	106	0.09	0.07
Specimen -7	242	107	0.08	0.07
Specimen -8	242	106	0.08	0.07
Specimen -9	241	106	0.09	0.06
Specimen -10	240	105	0.09	0.07
Specimen -11	242	107	0.09	0.06
Specimen -12	243	105	0.08	0.06
Specimen -13	240	107	0.09	0.07
Requirement	Min: 230 mm	Min: 110mm±10	Min: 0.05 mm	Min: 0.05 mm

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4. PHYSICAL PROPERTIES
ASTM D412-16 (Die C)

Type of Machine Used: CRE

Ageing Condition: Temp: (70±2) °C / Duration: 166 ± 2 hours

	Before accelerated ageing		After accelerated ageing	
	Tensile strength (Mpa)	Ultimate elongation (%)	Tensile strength (Mpa)	Ultimate elongation (%)
Specimen -1	23.4	642.0	17.8	601.7
Specimen -2	25.8	659.2	16.2	588.3
Specimen -3	19.2	626.0	14.3	545.0
Specimen -4	14.9	569.8	14.4	540.0
Specimen -5	17.7	561.8	16.1	578.3
Specimen -6	14.0	604.9	14.8	561.7
Specimen -7	17.3	586.4	16.0	566.7
Specimen -8	18.7	600.0	14.2	581.7
Specimen -9	16.7	615.3	15.2	571.7
Specimen -10	14.0	549.3	14.5	531.7
Specimen -11	18.8	612.8	19.0	531.7
Specimen -12	15.3	588.7	18.1	540.0
Specimen -13	18.7	666.9	18.7	508.3
Mean	--	--	16.1	557.4
Requirement	Min: 14.0 MPa	Min: 650%	Min: 14.0 MPa	Min: 400%

Note: Above all requirements given as per ASTM D6319-19 (Clause 7.5)

Remark: The tests were performed by SGS India Lab.

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PHOTO OF SUBMITTED SAMPLE FOR TESTING (*)



REPORT RESULTS REFER TO SUBMITTED SAMPLE (S) ONLY
End of Report

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THE WORLD INVESTMENT DEVELOPMENT JOIN STOCK COMPANY

NO 164 TRIEU VIET VUONG –NGUYEN DU WARD –HAI BA TRUNG DIST- HA NOI- VIET NAM

The following sample was submitted and identified on behalf of the client as below:

SGS Job No. : VNHL2008016569HG
Sample Description : NITRILE EXAMINATION MEDICAL GLOVE – POWDER FREE
Color : “XANH”
Characteristic : “CAO SU NHAN TAO / NITRILE”
Country of Origin : VIETNAM
Country of Destination : USA, EU, ASIA
Item/ Style# : 1
Date of Production : 07/2020
Manufacturer : THE WORLD INVESTMENT DEVELOPMENT JOIN STOCK COMPANY
End Users : ADULTS
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Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Results : PLEASE REFER TO NEXT PAGE(S).

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Test Method / Standard	Summary of Test Results/Conclusion	
	Clause/Test Name	Status / Performance Level
EN 16523-1:2015	Permeation by Liquid chemical under conditions of continuous contact.	
	Methanol	Level – 0
	Acetone	Level – 0
	Acetonitrile	Level – 0
	Sodium hydroxide	Level – 6
	Formaldehyde	Level – 1
EN ISO 374-4:2019	Resistance to Degradation by Chemicals	
	Methanol	Refer results.
	Acetone	Refer results.
	Acetonitrile	Refer results.
	Sodium hydroxide	Refer results.
	Formaldehyde	Refer results.
EN ISO 374-2:2019	Protective gloves against chemicals and micro-organisms: Determination of resistance penetration	
	Clause 4.1 – Air leak test	Pass
	Clause 4.2 – Water leak test	Pass

Signed for and on behalf of

SGS Vietnam LTD

Ung Thanh Van
 Hardline Lab Manager

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Test results

Sample Description: 1. NITRILE EXAMINATION MEDICAL GLOVE – POWDER FREE

EN 16523-1:2015 Determination of material resistance to permeation by chemicals – Part-1: Permeation by Liquid chemical under conditions of Continuous contact.

Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR 1.0 µg cm-2 min-1 (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Methnol 67-56-1	Closed loop/ Nitrogen	Continuous measurement With GC-FID	0.07 0.07 0.07	1 2 1	Level – 0	Moderate Swelling
Acetone 67-64-1	Closed loop/ Nitrogen	Continuous measurement With GC-FID	0.07 0.07 0.07	<1 <1 <1	Level – 0	Severe Swelling
Acetonitrile 75-05-8	Closed loop/ Nitrogen	Continuous measurement With GC-FID	0.07 0.07 0.07	<1 <1 <1	Level – 0	Severe Swelling
Sodium hydroxide 1310-73-2	Closed loop/ Grade 3 Water	Continuous measurement With electrode	0.07 0.07 0.07	>480 >480 >480	Level – 6	No Change
Formaldehyde 50-00-0 37%	Closed loop/ Grade 3 Water	Continuous measurement With electrode	0.07 0.07 0.07	22 24 21	Level – 1	Moderate Swelling

EN ISO 374-1:2016 – Protective gloves against dangerous chemicals and micro-organisms.
Part 1: Terminology and performance requirements for chemical risks.
Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

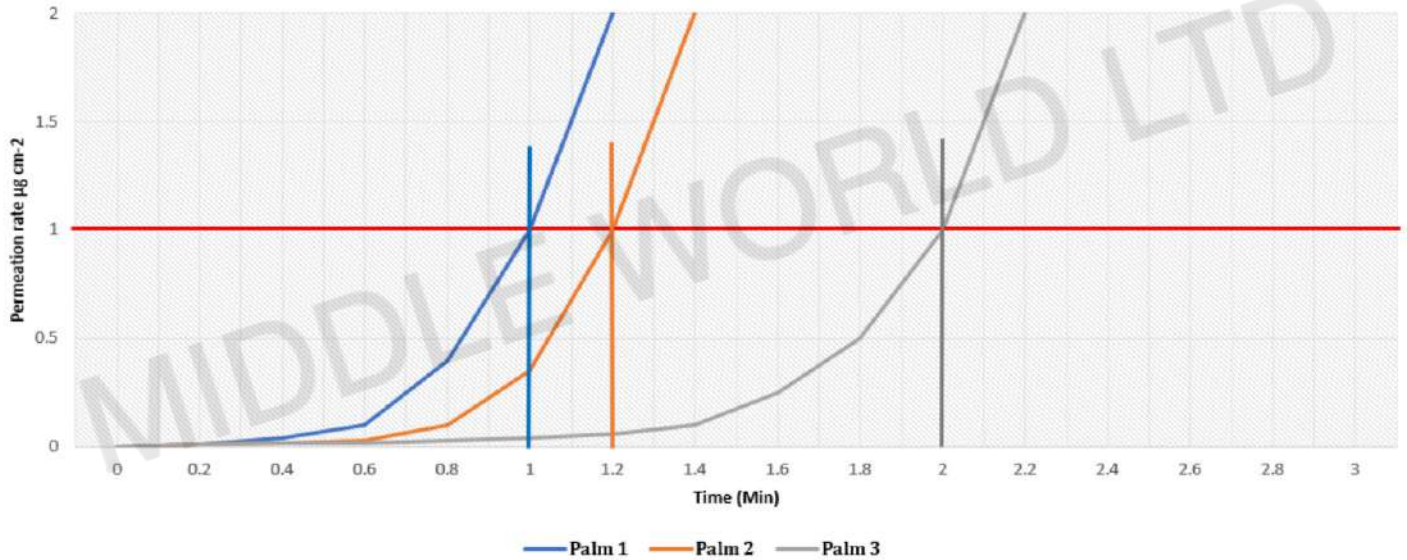
Performance levels are based on the lowest individual results achieved per chemical

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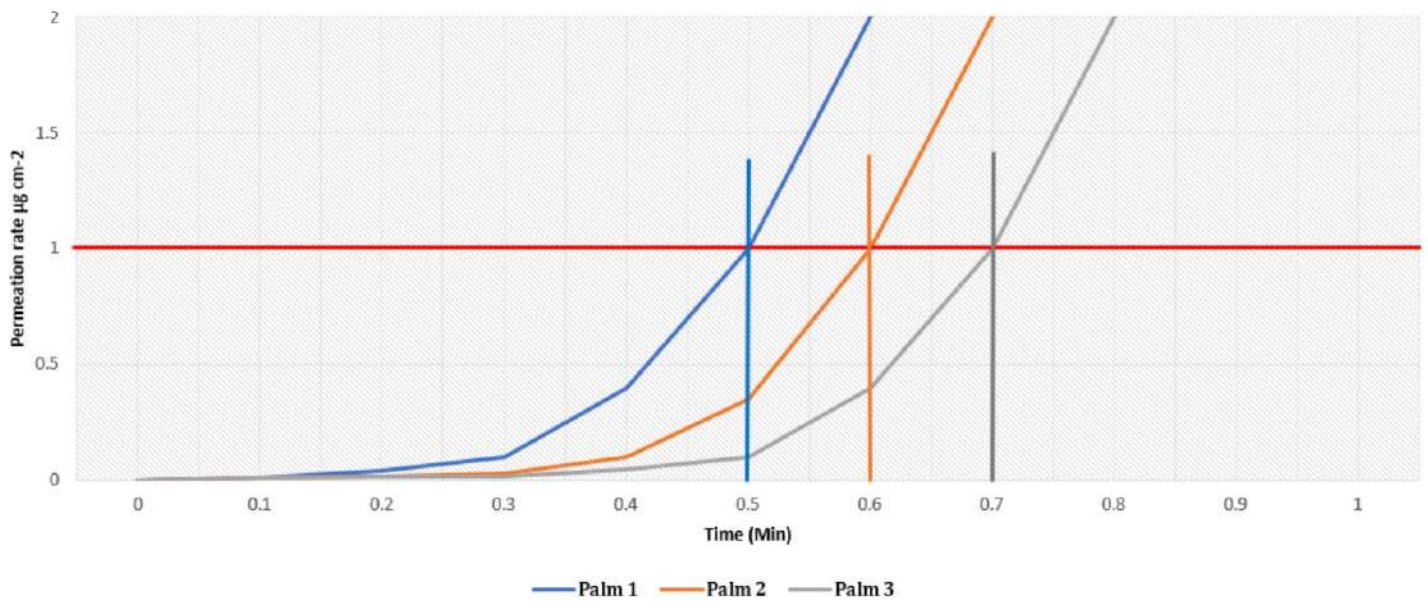
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Methanol Permeation Graph



Acetone Permeation Graph

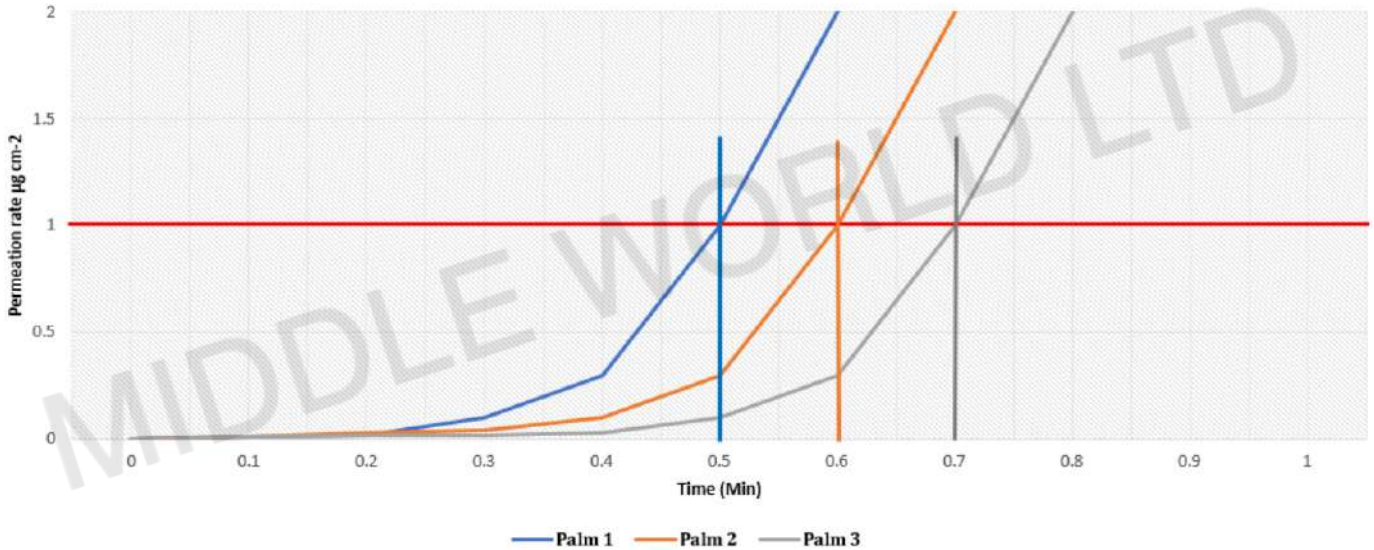


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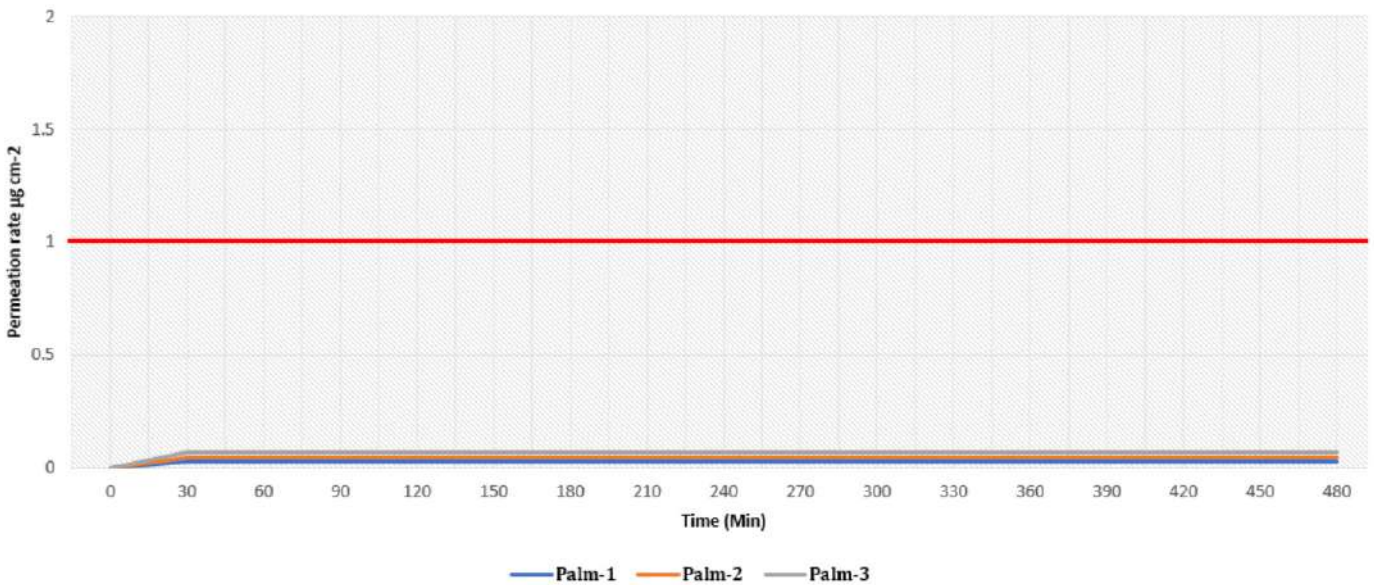
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Acetonitrile Permeation Graph



Sodium Hydroxide 40% Permeation Graph

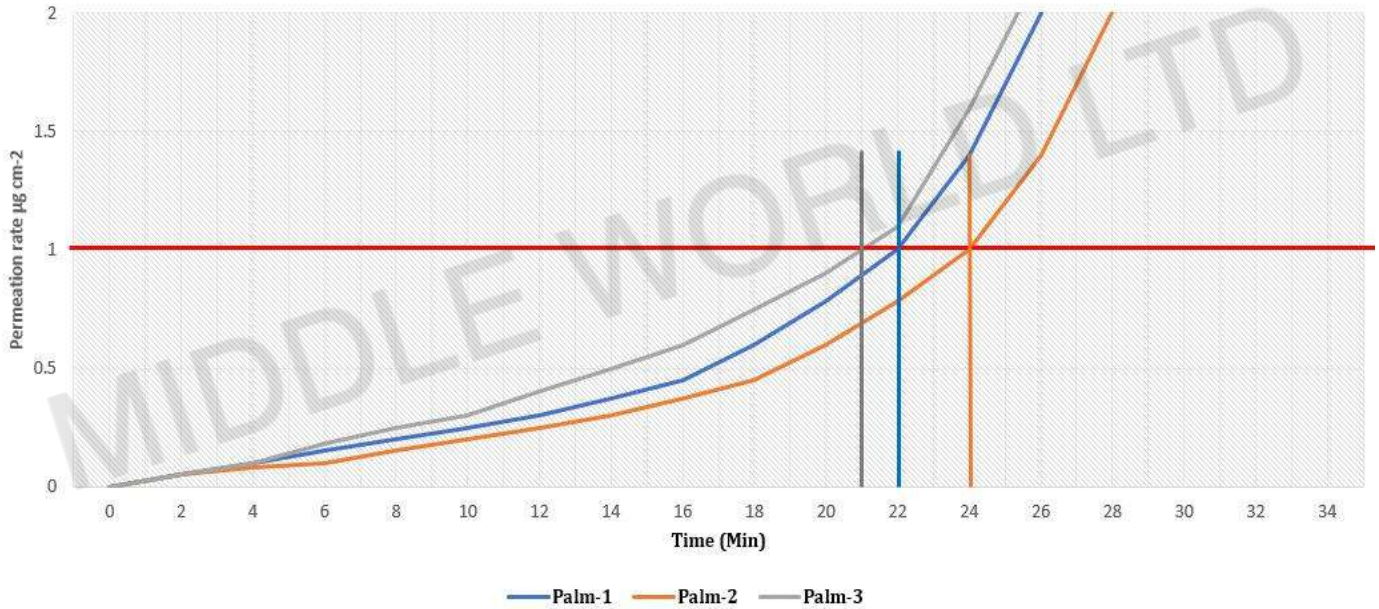


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Formaldehyde 37% Permeation Graph



EN ISO 374-2 : 2019 Protective gloves against chemicals and micro-organisms – Part-2: Determination of resistance penetration

Clause	Test Name	Test Results		Performance level
5.2	Air leak Test (Air Pressure Used: 0.5kPa)	Sample	Leakage	Pass
		M	No Leakage	
		M	No Leakage	
		M	No Leakage	
5.3	Water leak test	Sample Size	Leakage	Pass
		M	No Leakage	
		M	No Leakage	
		M	No Leakage	

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EN ISO 374-4:2019 Protective Gloves against Chemicals and Micro Organisms – Determination of resistance to degradation by chemicals

Chemical / CAS NO	Exposure Duration	Test Results		Observation
		Percentage change in puncture resistance		
Methanol 67-56-1	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Severe Swelling
		1	78.1	
		2	78.1	
		3	78.4	
		Mean	78.2	
Standard Deviation	0.188			
Acetone 67-64-1	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Severe Swelling
		1	84.3	
		2	83.8	
		3	84.8	
		Mean	84.3	
Standard Deviation	0.490			
Acetonitrile 75-05-8	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Severe Swelling
		1	82.0	
		2	81.8	
		3	82.2	
		Mean	82.0	
Standard Deviation	0.170			
Sodium hydroxide 40% 1310-73-2	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	No Change
		1	28.6	
		2	29.3	
		3	26.9	
		Mean	28.3	
Standard Deviation	1.276			
Formaldehyde 50-00-0 37%	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Moderate Swelling
		1	46.8	
		2	47.1	
		3	46.7	
		Mean	46.9	
Standard Deviation	0.235			

Remark: The tests were performed by SGS India Lab.

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PHOTO OF SUBMITTED SAMPLE FOR TESTING (*)



REPORT RESULTS REFER TO SUBMITTED SAMPLE (S) ONLY
*****End of Report*****

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Test Report

No. VNHL2008016568HG

Date: October 09, 2020

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THE WORLD INVESTMENT DEVELOPMENT JOIN STOCK COMPANY NO 164 TRIEU VIET VUONG –NGUYEN DU WARD –HAI BA TRUNG DIST- HA NOI- VIET NAM

The following sample was submitted and identified on behalf of the client as below:

SGS Job No. : VNHL2008016568HG
Sample Description : NITRILE EXAMINATION MEDICAL GLOVE – POWDER FREE
Color : "XANH"
Characteristic : "CAO SU NHAN TAO / NITRILE"
Country of Origin : VIETNAM
Country of Destination : USA, EU, ASIA
Item/ Style# : 1
Date of Production : 07/2020
Manufacturer : THE WORLD INVESTMENT DEVELOPMENT JOIN STOCK COMPANY
End Users : ADULTS
Sample Receiving Date : AUGUST 28, 2020
Final confirmed Date : AUGUST 28, 2020
Testing Period : AUGUST 28, 2020 TO OCTOBER 09, 2020
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Results : PLEASE REFER TO NEXT PAGE(S).

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Summary of Test Results/Conclusion		
Test Method / Standard	Clause/Test Name	Status / Performance Level
EN 455-1:2000	Medical gloves for single use	
	Freedom from holes	Pass
EN 455-2:2015	Dimensions	Pass
EN 455-3:2015	Protein Content	Refer Results
	Powder Content	Pass

Signed for and on behalf of

SGS Vietnam LTD



Ung Thanh Van

Hardline Lab Manager

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Test Report

No. VNHL2008016568HG

Date: October 09, 2020

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Test results (*)

Sample Description: 1. NITRILE EXAMINATION MEDICAL GLOVE – POWDER FREE

**MEDICAL GLOVES FOR SINGLE USE -
BREAKING STRENGTH EN 455-2:2015**
(Method:5.2 & 5.3) Type of Machine Used: CRE

Ageing condition

Temperature: (70 ± 2) °C.
Duration: 7 Days.

	As Received Force at break (N)	After challenge testing Force at break (N)
Specimen -1	5.6	5.3
Specimen -2	6.4	5.9
Specimen -3	2.9	2.9
Specimen -4	6.2	6.2
Specimen -5	2.6	2.5
Specimen -6	6.1	6.0
Specimen -7	6.5	6.4
Specimen -8	3.6	3.3
Specimen -9	6.9	6.3
Specimen -10	5.3	4.4
Specimen -11	4.6	3.6
Specimen -12	6.8	5.8
Specimen -13	5.1	4.5
Mean Force at Break In N	4.9	4.8
Average thickness of the test specimen is :	0.07	

Requirement

	Force at Break in N		
	Surgical Glove	Examination Glove	
	a)	b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥9.0	≥6.0	≥3.6
Requirements for all surgical gloves.			
Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)..			
Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			

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**MEDICAL GLOVES FOR SINGLE USE - DIMENSIONS**
EN 455-2:2015 (Method:4.2 & 4.3)

	Dimension (mm)	
	Size: Medium	
	Length	Width
Specimen -1	243	96
Specimen -2	244	95
Specimen -3	244	94
Specimen -4	245	96
Specimen -5	243	95
Specimen -6	244	95
Specimen -7	242	94
Specimen -8	245	96
Specimen -9	244	95
Specimen -10	246	94
Specimen -11	244	93
Specimen -12	243	94
Specimen -13	244	95
Requirement	≥ 240	95±10

MEDICAL GLOVES FOR SINGLE USE – FREEDOM FROM HOLES EN 455-1:2000 (Method:5.1)

Sample Size:	200 pcs
Number of non-confirming gloves:	6 pcs
Acceptable Number of non-confirming gloves:	7 pcs

Note: Sampling was carried out as per ISO 2859-1 AQL of 1.5, General inspection level 1 and sample code letter L.

MEDICAL GLOVES FOR SINGLE USE – EXTRACTABLE PROTEIN CONTENT
With Reference To EN 455-3:2015

PROTEIN CONTENT ND

Note: ND – Not Detected; Method Detection Limit = 10 ppm

MEDICAL GLOVES FOR SINGLE USE – POWDER CONTENT EN 455-3:2015 (Method:5.2)

Powder content per glove 0.5 mg Max: 2.0 mg

Note: Requirements are given as per EN 455-3:2015 (Clause: 4.4).

Remark: The tests were performed by SGS India Lab.

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PHIẾU KẾT QUẢ THỬ NGHIỆM
TEST REPORT

07/10/2020

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1. Tên mẫu : **GĂNG TAY CAO SU Y TẾ KHÁM BỆNH THE WORLD**
Name of sample **NITRILE KHÔNG BỘT - SIZE L**
MODEL : TW.NITRILE
2. Mô tả mẫu : Mẫu thử nghiệm do khách hàng lấy mẫu, tên mẫu và thông tin về mẫu do khách hàng cung cấp. / *Testing sample was sampled by customer, sample name and sample information were supplied by customer.*
Description Khoảng 50 cái găng tay màu xanh dương / *blue rubber glove*
3. Số lượng mẫu : 01
Quantity
4. Ngày nhận mẫu : 22/09/2020
Date of receipt
5. Thời gian thử nghiệm : 23/09/2020 - 07/10/2020
Testing duration
6. Nơi gửi mẫu : **CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD**
Customer **Số 164, phố Triệu Việt Vương, Phường Nguyễn Du, Quận Hai Bà Trưng, Thành phố Hà Nội**
7. Kết quả thử nghiệm : Xem các trang tiếp theo
Test results *Refer to next pages*

P. TRƯỞNG PTN HÀNG TIÊU DÙNG
DEPUTY HEAD OF CONSUMER
PRODUCTS TESTING LAB.



Nguyễn Thị Thùy Nhi

TL. GIÁM ĐỐC/ PP. DIRECTOR
TRUNG TÂM KỸ THUẬT TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3
HEAD OF TESTING LAB.



Ngô Quốc Việt

1. Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến và không phải là giấy chứng nhận sản phẩm.
Test results are valid for the namely submitted sample(s) only, and this is not a certificate of product.
2. Không được trích sao một phần phiếu kết quả thử nghiệm này nếu không có sự đồng ý bằng văn bản của Trung tâm Kỹ thuật 3.
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3. Tên mẫu, tên khách hàng được ghi theo yêu cầu của nơi gửi mẫu. / *Name of sample(s) and customer are written as customer's request.*
4. Độ không đảm bảo đo mở rộng ước lượng được tính với $k = 2$, mức tin cậy 95 %.
Estimated expanded uncertainty of measurement with $k = 2$, at 95 % confidence level.
5. Mọi thắc mắc về kết quả khách hàng liên hệ theo địa chỉ dh.cs@quatest3.com.vn và rq.tn@quatest3.com.vn để biết thêm thông tin.
Please contact Quatest 3 at the email addresses dh.cs@quatest3.com.vn and rq.tn@quatest3.com.vn for further information about test report.

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PHIẾU KẾT QUẢ THỬ NGHIỆM

TEST REPORT



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Tên chỉ tiêu <i>Characteristic</i>	Đơn vị tính <i>Unit</i>	Phương pháp thử <i>Test method</i>	Giới hạn phát hiện/ <i>limit of detection</i>	Kết quả thử nghiệm <i>Test result</i>	Mức yêu cầu/ <i>Requirement</i> (*)
7.1 Định danh cao su bằng phương pháp phổ hồng ngoại/ <i>Identification of rubber by infrared spectroscopy method</i>	-	ASTM E 1252 - 98	-	Cao su nitrile	
THỬ VẬT LIỆU/ MATERIAL TEST					
7.2 Hàm lượng chì/ <i>Lead content</i>	µg/g	QCVN 12-2 : 2011/BYT	5,0	KPH/ND	≤ 100
7.3 Hàm lượng cadimi/ <i>Cadmium content</i>	µg/g	QCVN 12-2 : 2011/BYT	5,0	KPH/ND	≤ 100
7.4 Thử 2-Mercapto imidazoline / 2- <i>Mercapto imidazoline test</i>	-	QCVN 12-2 : 2011/BYT	-	N/A	Âm tính <i>Negative</i>
THỬ NGÂM THÔI NHIỄM/ ELUTION TEST					
7.5 Hàm lượng phenol trong nước sau 30 phút ở 60 °C/ <i>Phenol content in water after 30 min at 60 °C,</i>	µg/mL	QCVN 12-2 : 2011/BYT	-	< 5	≤ 5
7.6 Thử formaldehyde trong nước sau 30 phút ở 60 °C/ <i>Formaldehyde test in water after 30 min at 60 °C,</i>	-	QCVN 12-2 : 2011/BYT	-	Âm tính <i>Negative</i>	Âm tính <i>Negative</i>
7.7 Hàm lượng kẽm trong acetic acid 4% (v/v) sau 30 phút ở 60 °C/ <i>Zinc content in 4% acetic acid (v/v) after 30 min at 60 °C,</i>	µg/mL	QCVN 12-2 : 2011/BYT	1,0	4,1	≤ 15
7.8 Kim loại nặng (quy ra chì) trong acetic acid 4% sau 30 phút ở 60 °C/ <i>Heavy metals (as Pb) in 4% acetic acid after 30 min at 60 °C,</i>	µg/mL	QCVN 12-2 : 2011/BYT	-	< 1,0	≤ 1
7.9 Hàm lượng cặn khô / <i>Evaporation residue,</i>		QCVN 12-2 : 2011/BYT			
• Trong nước sau 30 phút ở 60 °C/ <i>In water after 30 min at 60 °C,</i>	µg/mL		5,0	20,0	≤ 60
• Trong acetic acid 4% (v/v) sau 30 phút ở 60 °C/ <i>In 4% acetic acid (v/v) after 30 min at 60 °C,</i>	µg/mL		5,0	32,3	≤ 60
• Trong ethanol 20 % (v/v) sau 30 phút ở 60 °C/ <i>In 20 % ethanol (v/v) after 30 min at 60 °C</i>	µg/mL		5,0	27,0	≤ 60

1. Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến và không phải là giấy chứng nhận sản phẩm.

Test results are valid for the namely submitted sample(s) only, and this is not a certificate of product.

2. Không được trích sao một phần phiếu kết quả thử nghiệm này nếu không có sự đồng ý bằng văn bản của Trung tâm Kỹ thuật 3.

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3. Tên mẫu, tên khách hàng được ghi theo yêu cầu của nơi gửi mẫu. / *Name of sample(s) and customer are written as customer's request.*

4. Độ không đảm bảo do mở rộng ước lượng được tính với k = 2, mức tin cậy 95%.

Estimated expanded uncertainty of measurement with k = 2, at 95 % confidence level.

5. Mọi thắc mắc về kết quả khách hàng liên hệ theo địa chỉ dh.cs@quatest3.com.vn và rq.tn@quatest3.com.vn để biết thêm thông tin.

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PHIẾU KẾT QUẢ THỬ NGHIỆM
TEST REPORT

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Ghi chú/ Note:

Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến/ *Test results are valid for the namely submitted sample only.*

(*) - Theo yêu cầu kỹ thuật của QCVN 12-2 : 2011/BYT / *According to Technical specification of QCVN 12-2 : 2011/BYT*

KPH/ND : Không phát hiện/ *Not detected*

(N/A) - Không áp dụng / *Not applicable*



1. Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến và không phải là giấy chứng nhận sản phẩm.
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4. Độ không đảm bảo đo mở rộng ước lượng được tính với $k = 2$, mức tin cậy 95 %.
Estimated expanded uncertainty of measurement with $k = 2$, at 95 % confidence level.
5. Mọi thắc mắc về kết quả khách hàng liên hệ theo địa chỉ dh.cs@quatest3.com.vn và rq.tn@quatest3.com.vn để biết thêm thông tin.
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PHIẾU KẾT QUẢ THỬ NGHIỆM
TEST REPORT

07/10/2020

Page: 01/03

1. Tên mẫu : **GĂNG TAY CAO SU Y TẾ KHÁM BỆNH THE WORLD**
Name of sample **NITRILE KHÔNG BỘT - SIZE L**
MODEL : TW.NITRILE
2. Mô tả mẫu : **Mẫu thử nghiệm do khách hàng lấy mẫu, tên mẫu và thông tin về mẫu do**
Description **khách hàng cung cấp. / Testing sample was sampled by customer, sample**
name and sample information were supplied by customer.
Khoảng 50 cái găng tay màu xanh dương / blue rubber glove
3. Số lượng mẫu : 01
Quantity
4. Ngày nhận mẫu : 22/09/2020
Date of receipt
5. Thời gian thử nghiệm : 23/09/2020 - 07/10/2020
Testing duration
6. Nơi gửi mẫu : **CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD**
Customer **Số 164, phố Triệu Việt Vương, Phường Nguyễn Du, Quận Hai Bà**
Trung, Thành phố Hà Nội
7. Kết quả thử nghiệm : Xem các trang tiếp theo
Test results **Refer to next pages**

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PRODUCTS TESTING LAB.



Nguyễn Thị Thùy Nhi

TL. GIÁM ĐỐC / PP. DIRECTOR
TRƯỞNG PHÒNG THỬ NGHIỆM
HEAD OF TESTING LAB.



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4. Độ không đảm bảo đo mở rộng ước lượng được tính với $k = 2$, mức tin cậy 95 %.
Estimated expanded uncertainty of measurement with $k = 2$, at 95 % confidence level.
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Tên chỉ tiêu <i>Characteristic</i>	Đơn vị <i>Unit</i>	Phương pháp thử <i>Test method</i>	Giới hạn phát hiện/ <i>limit of detection</i>	Kết quả thử nghiệm <i>Test result</i>	Mức yêu cầu/ <i>Requirement</i> (*)
7.1 Định danh cao su bằng phương pháp phổ hồng ngoại/ <i>Identification of rubber by infrared spectroscopy method</i>	-	ASTM E 1252 - 98	-	Cao su nitrile	
THỬ VẬT LIỆU/ MATERIAL TEST					
7.2 Hàm lượng chì/ <i>Lead content</i>	µg/g	QCVN 12-2 : 2011/BYT	5,0	KPH/ND	≤ 100
7.3 Hàm lượng cadimi/ <i>Cadmium content</i>	µg/g	QCVN 12-2 : 2011/BYT	5,0	KPH/ND	≤ 100
7.4 Thử 2-Mercapto imidazoline / <i>2-Mercapto imidazoline test</i>	-	QCVN 12-2 : 2011/BYT	-	N/A	Âm tính <i>Negative</i>
THỬ NGẮM THÔI NHIỄM/ ELUTION TEST					
7.5 Hàm lượng phenol trong nước sau 30 phút ở 60 °C/ <i>Phenol content in water after 30 min at 60 °C,</i>	µg/mL	QCVN 12-2 : 2011/BYT	-	< 5	≤ 5
7.6 Thử formaldehyde trong nước sau 30 phút ở 60 °C/ <i>Formaldehyde test in water after 30 min at 60 °C,</i>	-	QCVN 12-2 : 2011/BYT	-	Âm tính <i>Negative</i>	Âm tính <i>Negative</i>
7.7 Hàm lượng kẽm trong acetic acid 4% (v/v) sau 30 phút ở 60 °C/ <i>Zinc content in 4% acetic acid (v/v) after 30 min at 60 °C,</i>	µg/mL	QCVN 12-2 : 2011/BYT	1,0	4,1	≤ 15
7.8 Kim loại nặng (quy ra chì) trong acetic acid 4% sau 30 phút ở 60 °C/ <i>Heavy metals (as Pb) in 4% acetic acid after 30 min at 60 °C,</i>	µg/mL	QCVN 12-2 : 2011/BYT	-	< 1,0	≤ 1
7.9 Hàm lượng cặn khô / <i>Evaporation residue,</i>		QCVN 12-2 : 2011/BYT			
• Trong nước sau 30 phút ở 60 °C/ <i>In water after 30 min at 60 °C,</i>	µg/mL		5,0	20,0	≤ 60
• Trong acetic acid 4% (v/v) sau 30 phút ở 60 °C/ <i>In 4% acetic acid (v/v) after 30 min at 60 °C,</i>	µg/mL		5,0	32,3	≤ 60
• Trong ethanol 20 % (v/v) sau 30 phút ở 60 °C/ <i>In 20 % ethanol (v/v) after 30 min at 60 °C</i>	µg/mL		5,0	27,0	≤ 60

1. Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến và không phải là giấy chứng nhận sản phẩm.
Test results are valid for the sample submitted only, and this is not a certificate of product.

2. Không được trích sao một phần phiếu kết quả thử nghiệm này nếu không có sự đồng ý bằng văn bản của Trung tâm Kỹ thuật 3.
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3. Tên mẫu, tên khách hàng được ghi theo yêu cầu của nơi gửi mẫu. / *Name of sample(s) and customer are written as customer's request.*

4. Độ không đảm bảo đo mở rộng ước lượng được tính với k = 2, mức tin cậy 95 %.
Estimated expanded uncertainty of measurement with k = 2, at 95 % confidence level.

5. Mọi thắc mắc về kết quả khách hàng liên hệ theo địa chỉ dh.cs@quatest3.com.vn và ng.tn@quatest3.com.vn để biết thêm thông tin.

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KT3-05373AHD0/3

PHIẾU KẾT QUẢ THỬ NGHIỆM TEST REPORT



07/10/2020

Page: 02/03

Ghi chú/ Note:

Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến/ *Test results are valid for the namely submitted sample only.*

(*) - Theo yêu cầu kỹ thuật của QCVN 12-2 : 2011/BYT / *According to Technical specification of QCVN 12-2 : 2011/BYT*

KPH/ND : Không phát hiện/ *Not detected*

(N/A) - Không áp dụng / *Not applicable*



1. Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến và không phải là giấy chứng nhận sản phẩm.

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4. Độ không đảm bảo do mở rộng ước lượng được tính với $k = 2$, mức tin cậy 95 %.

Estimated expanded uncertainty of measurement with $k = 2$, at 95 % confidence level.

5. Mọi thắc mắc về kết quả khách hàng liên hệ theo địa chỉ dh.cs@quatest3.com.vn và rq.tn@quatest3.com.vn để biết thêm thông tin.

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TỔNG CỤC TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG
TRUNG TÂM KỸ THUẬT TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3
QUALITY ASSURANCE & TESTING CENTER 3

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Testing: No. 7, road No. 1, Bien Hoa 1 IZ, Dong Nai, Vietnam
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Tel: (84-251) 383 6212
Tel: (84-28) 3742 3160

Fax: (84-28) 3829 3012
Fax: (84-251) 383 6298
Fax: (84-28) 3829 3012

Website: www.quatest3.com.vn
E-mail: dh.cs@quatest3.com.vn
E-mail: dh.cs@quatest3.com.vn

KT3-05373AHD0/1/R

PHIẾU KẾT QUẢ THỬ NGHIỆM
TEST REPORT

19/10/2020

Page: 01/03

- Tên mẫu
Name of sample : **GĂNG TAY CAO SU Y TẾ KHÁM BỆNH THE WORLD
NITRILE KHÔNG BỘT - SIZE L
MODEL : TW.NITRILE SIZE L**
- Mô tả mẫu
Description : Mẫu thử nghiệm do khách hàng lấy mẫu, tên mẫu và thông tin về mẫu do khách hàng cung cấp. / Testing sample was sampled by customer, sample name and sample information were supplied by customer.
Khoảng 50 cái găng tay màu xanh dương, size L / blue rubber glove
- Số lượng mẫu
Quantity : 01
- Ngày nhận mẫu
Date of receipt : 22/09/2020
- Thời gian thử nghiệm
Testing duration : 23/09/2020 - 19/10/2020
- Nơi gửi mẫu
Customer : **CÔNG TY CỔ PHẦN ĐẦU TƯ DEVELOPMENT THE WORLD
Số 164, phố Triệu Việt Vương, Phường Nguyễn Du, Quận Hai Bà
Trung, Thành phố Hà Nội**
- Kết quả thử nghiệm
Test results : Xem các trang tiếp theo
Refer to next pages

P.TRƯỞNG PTN HÀNG TIÊU DÙNG
DEPUTY HEAD OF CONSUMER
PRODUCTS TESTING LAB.

Nguyễn Thị Thùy Nhi

TL. GIÁM ĐỐC/ PP. DIRECTOR
TRƯỞNG PHÒNG THỬ NGHIỆM
HEAD OF TESTING LAB.



Phan Thanh Trung

- Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến và không phải là giấy chứng nhận sản phẩm.
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- Độ không đảm bảo đo mở rộng ước lượng được tính với $k = 2$, mức tin cậy 95 %.
Estimated expanded uncertainty of measurement with $k = 2$, at 95 % confidence level.
- Mọi thắc mắc về kết quả khách hàng liên hệ theo địa chỉ dh.cs@quatest3.com.vn và rq.tn@quatest3.com.vn để biết thêm thông tin.
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KT3-05373AHD0/1/R

PHIẾU KẾT QUẢ THỬ NGHIỆM
TEST REPORT



19/10/2020

Page: 02/03

Chế độ lão hóa : nhiệt độ 70 °C, thời gian 168 giờ
Ageing condition: at 70 °C for 168 hours

Tên chỉ tiêu <i>Characteristic</i>	Phương pháp thử <i>Test method</i>	Kết quả thử nghiệm <i>Test result</i>			
		Lượng găng thử/ <i>Quantity of specimen</i>	Giá trị trung binh/ <i>Mean</i>	Giá trị nhỏ nhất/ <i>Min</i>	Giá trị lớn nhất/ <i>Max</i>
7.1 Lực kéo đứt / <i>Force at break</i> , N	TCVN 4509: 2013				
• Trước lão hoá/ <i>Before ageing</i>		3	6,83	5,33	7,97
• Sau lão hoá/ <i>After ageing</i>		3	6,55	5,64	7,54
7.2 Độ dẫn dài khi đứt/ <i>Elongation at break</i> , %	TCVN 4509: 2013				
• Trước lão hoá/ <i>Before ageing</i>		3	489	476	501
• Sau lão hoá/ <i>After ageing</i>		3	488	458	516
7.3 Kích thước/ <i>Dimensions</i> , mm	TCVN 6343-1: 2007	3			
• Rộng/ <i>Width</i> ,			109	108	109
• Dài/ <i>Length</i> ,			249	248	250
• Dày tại các vị trí/ <i>Thickness at</i> , mm					
a. Ngón tay/ <i>Finger</i>			0,11	0,10	0,11
b. Lòng bàn tay/ <i>Palm</i>			0,07	0,07	0,07
7.4 Thử lỗ thủng/ <i>Watertightness</i> , số găng hư / <i>number of defects</i>	TCVN 6343-1: 2007	3			Không rò rỉ <i>No leakage</i>

Ghi chú/ Note: - Số lượng găng thử: theo yêu cầu khách hàng/ *The number of test specimen has been specified by customer.*

- Các kết quả thử nghiệm ghi trong phiếu này chỉ có giá trị đối với mẫu do khách hàng gửi đến và không phải là giấy chứng nhận sản phẩm.
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KT3-05373AHD0/1/R

PHIẾU KẾT QUẢ THỬ NGHIỆM
TEST REPORT



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4. Độ không đảm bảo đo mở rộng ước lượng được tính với $k = 2$, mức tin cậy 95 %.
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**GIẤY CHỨNG NHẬN
THỬ NGHIỆM**

Số: 299420 /VTTB-ĐGCL

Cơ quan yêu cầu: Công ty Cổ phần Đầu tư Development The World

Địa chỉ: Số 164, phố Triệu Việt Vương, Phường Nguyễn Du, Quận Hai Bà Trưng, Thành phố Hà Nội

Tên sản phẩm: Găng tay cao su y tế The World

Model: Nitrile không bột size L

Đơn vị sản xuất: Công ty Cổ phần Đầu tư Development The World

Xuất xứ: Việt Nam

Người thử nghiệm: Trần Đức Anh

Tiêu chuẩn thử nghiệm: Theo tiêu chuẩn cơ sở TCCS 01:2020/TW

Kết luận: Găng tay đạt theo tiêu chuẩn cơ sở TCCS 01:2020/TW.

Hà Nội, ngày 09 tháng 7 năm 2020

VIỆN TRƯỞNG



TS. Lê Thanh Hải

KẾT QUẢ THỬ NGHIỆM

Thông số kỹ thuật

TT	Nội dung	Yêu cầu	Kết quả đo / thử nghiệm				Đạt	K.Đạt
			Lần 1	Lần 2	Lần 3	Trung bình		
1	Kích thước, mm		Dài: 239 Rộng: 107 Dày: - Ngón tay: 0,12 - Lòng bàn tay: 0,081	Dài: 240 Rộng: 107 Dày: - Ngón tay: 0,12 - Lòng bàn tay: 0,081	Dài: 240 Rộng: 108 Dày: - Ngón tay: 0,12 - Lòng bàn tay: 0,081	Dài: 240 Rộng: 107 Dày: - Ngón tay: 0,12 - Lòng bàn tay: 0,081	X	
2	Vật liệu	Cao su nitrile	Găng tay bằng cao su nitrile				X	
3	Cấu tạo	Bề mặt trơn nhẵn, ngón tay nhám	Bề mặt ngoài của găng tay nhẵn, các đầu ngón tay nhám				X	
4	Độ kín nước		Không có hiện tượng rò rỉ nước				X	
5	Độ bền kéo							
5.1	Lực kéo đứt tối thiểu trước khi già hóa nhanh, N	6,5	8,3	8,5	8,5	8,5	X	
5.2	Độ giãn dài tối thiểu khi đứt trước khi già hóa nhanh, %	500	538	532	535	535	X	
5.3	Lực kéo đứt tối thiểu sau khi già hóa nhanh, N	6,0	7,4	7,4	7,5	7,4	X	
5.4	Độ giãn dài tối thiểu khi đứt sau khi già hóa nhanh, %	400	456	452	448	452	X	

* Kết quả thử nghiệm này chỉ có giá trị đối với các mẫu thử Công ty Cổ phần Đầu tư Development The World cung cấp cho Viện Trang thiết bị và Công trình Y tế ngày 06/7/2020.

SOÁT XÉT

Hà Nội, ngày 09 tháng 7 năm 2020

NGƯỜI THỬ NGHIỆM



Nguyễn Văn Hùng



Trần Đức Anh

FDA

Fiscal Year 2021

FDA REGISTRATION INFORMATION

This information that:

Guangdong Guyun Medical Technology Co., Ltd

Three Gorges resettlement group, jigongkeng village, Futian Town, BOLUO County, Huizhou City, Guangdong Province, China

has completed the FDA Establishment Registration(as foreign exporter)and Device Listing with the US Food&Drug Administration, through

**U.S.Agent for FDA
Communications:**

JOYSUN USA LLC
430 Oakbrook Dr, Columbus, IN 47201, USA.
Telephone: +13828842059 / E-mail: guyun@guyunmedical.com

Owner/Operator Number:10078809

Device Listing:

Listing No.	Code	Device Name
D424860	LYU	Disposable medical vinyl examination gloves
D424860	LYU	Disposable medical nitrile examination gloves
D424860	LYU	Disposable medical PVC/Nitrile examination gloves
D424860	LYU	Disposable PVC/Nitrile gloves
D424860	LYU	Disposable vinyl gloves
D424860	LYU	Disposable nitrile gloves

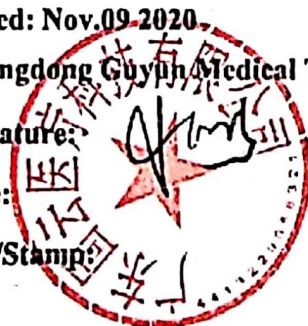
Issued: Nov.09.2020

Guangdong Guyun Medical Technology Co., Ltd

Signature:

Date:

Seal/Stamp:





EU-TYPE EXAMINATION CERTIFICATE



The following model of Personal Protective Equipment has been subjected to an EU type examination in accordance with the module B of the PPE regulation (2016/425) and has been shown to satisfy to essential health and safety requirements.

Certificate N° 0075/4184/162/12/20/3039

Issued by CTC, Notified Body N°0075, to the following model of personal protective equipment :

Manufacturer : Guangdong Guyun Medical Technology Co., Ltd.
Three Gorges resettlement group, jigongkeng village, Futian Town, BOLUO County, Huizhou City, Guangdong Province China

Description

PPE Type : protective glove against microorganisms risks

Product reference : Gug0101

Article code : /

Glove description : Disposable Nitrile gloves

Available sizes : 6/S 7/M 8/L 9/XL

Pictures :



Reference standard :

Levels of performance / class of protection

« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.
« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

EN ISO 21420:2020

-

EN ISO 374-5:2016

MICRO-ORGANISMS

This glove is intended to activity that does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent

At the date of certificate the product is in compliance with Annex XVII of REACH regulation (n° 1907/2006 and revisions)

Full description of the PPE, reference rules verified in the context of the EU-type examination and information given on the product are detailed in the manufacturer's technical file and the Instruction for Use index 01 dated from DECEMBER, 2020

NOTA : Any modification to new items of the personal protective equipment object of this EU type approval certificate or any modification of the information contained in the manufacturer technical file which served for the deliverance of the EU type approval certificate (change of address, change of company status) should be brought to the attention of the notified body in accordance with Annex V §7.2 of Regulation 2016/425. Any marking on the PPE which is not concerned by the Regulation (UE) 2016/425, is not covered by this certificate.

Issued in Lyon by
Didier GUISSADO

Date of first issue : 18 December 2020
End of validity date : 18 December 2025

Certification and Quality Manager



www.ctcgroupe.com

cemarking@ctcgroupe.com



Accreditation n° 5-0594
Scope available on:
www.cofrac.fr

CTC - 1, rue Hermann Frankel - 69267 Lyon cedex 07 - France
Tel : +33 (0)4 72 76 10 10 - Fax : +33 (0)4 72 76 10 00 - ctc@ctcgroupe.com

Comité Professionnel de Développement Économique (CPDE) Clair Chaussure Manufacturière Cantonale
Lot 78-654 du 22.06.1979 - Siret 77564972600160 - Code NAF 9412Z - TVA INTR BR/75649726



TEST REPORT



中国认可
国际互认
检测
TESTING
CNAS L4577

3F, Building Block 2, No. 3400 Gonghexin Road,
Jing'an District - Shanghai 200436, P.R. CHINA
上海市静安区共和新路3400号2幢3层
Tél. : +13828842059
Fax : +75521003895
E-mail : guyun@guyunmedical.com

Report No.: S200909121_2

28 October 2020

APPLICANT: GUANGDONG GUYUN MEDICAL TECHNOLOGY
CO., LTD 广东固云医疗科技有限公司
(C41545)

THREE GORGES RESETTLEMENT GROUP,
JIGONGKENG VILLAGE, FUTIAN TOWN,
BOLUO COUNTY,
HUIZHOU GUANGDONG
CHINA

jessic@ccgaomeng.com

Date of receipt : 08 Sept. 2020
Testing period : 08 Sept. 2020
: 11 Sept. 2020

Buyer: —

Sample description: Disposable Nitrile gloves

Reference no. : Gug0101

Test(s) requested : —

Service : REGULAR

Brand / Section : —

Season : —

End use : —

Factory name : —

Factory code : —

For CE Marking : Yes

Previous report : —

Product category : —

Product type : —

Test stage : FIRST TEST

Supplier name : —

Exported to : —

1. Conclusion:

	Tests description	Conformity
	EN ISO 21420/EN ISO 374-1	
1	pH - Textile (KCl solution)	Pass
2	Aromatic amines derived from azo colorants	Pass
3	Polycyclic Aromatic Hydrocarbons (8)	Pass
4	Dexterity	Level 5
5	Air Leak Test	Pass
6	Water Leak Test	Pass
7	XRF screening	Pass
8	XRF screening (Tin)	Pass

	Tests description	Conformity
9	Phthalates	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

This test report in version S200909121_2 supersedes the report S200909121_1

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To declare the conformity to the requirement, the uncertainty of measurement, associated to the test results, has not been taken into account.



Report No.: S200909121_2

28 October 2020

APPLICANT: GUANGDONG GUYUN MEDICAL TECHNOLOGY
CO., LTD 广东固云医疗科技有限公司
(C41545)

Approved by



Henry YAN
Laboratory Manager



Yvonne MAO
Senior Analytical Chemical Engineer

This test report in version S200909121_2 supersedes the report S200909121_1

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Report No.: S200909121_2

28 October 2020

APPLICANT: GUANGDONG GUYUN MEDICAL TECHNOLOGY
CO., LTD 广东固云医疗科技有限公司
(C41545)

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	Description	Sample information
	GLOVE	Whole glove blue nitrile palm	



200909121

This test report in version S200909121_2 supersedes the report S200909121_1

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Report No.: S200909121_2

28 October 2020

APPLICANT: GUANGDONG GUYUN MEDICAL TECHNOLOGY CO., LTD 广东固云医疗科技有限公司 (C41545)

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
5.2. Dexterity	EN ISO 21420: 2020				
Smallest diameter of pin fulfilling test condition			mm	5.0	
Smallest diameter of pin fulfilling test condition (2)			mm	5.0	
Smallest diameter of pin fulfilling test condition (3)			mm	5.0	
Smallest diameter of pin fulfilling test condition (4)			mm	5.0	
Performance level				5	
• Air Leak Test	EN 374-2:2019				Pass
Glove thickness			mm	0.10	
Air pressure used to test			kPa	3.5	
Result		No air bubbles		No air bubbles	
• Water Leak Test	EN 374-2:2019				Pass
Result		No water leak		No water leak	

blue nitrile palm

	Method	Client Requirement	Unit	Result	Conformity
(+) 4.2. pH - Textile (KCl solution)	ISO 3071:2020				Pass
pH value		3.5< - <9.5		8.3	
4.2. Aromatic amines derived from azo colorants	ISO 14362-1:2017 (w/o extraction)				Pass
Accessible without fibre extraction		<30	mg/kg	<5	
▲ 4.2. Polycyclic Aromatic Hydrocarbons (8)	ISO/TS 16190: 2013				Pass
Benzo(a)anthracene		<1	mg/kg	<0.1	
Chrysene		<1	mg/kg	<0.1	
Benzo(b)fluoranthene		<1	mg/kg	<0.1	
Benzo(k)fluoranthene		<1	mg/kg	<0.1	
Benzo(a)pyrene		<1	mg/kg	<0.1	
Dibenzo(a,h)anthracene		<1	mg/kg	<0.1	

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Report No.: S200909121_2

28 October 2020

APPLICANT: GUANGDONG GUYUN MEDICAL TECHNOLOGY
CO., LTD 广东固云医疗科技有限公司
(C41545)

	Method	Client Requirement	Unit	Result	Conformity
Benzo(e)pyrene		<1	mg/kg	<0.1	
Benzo(j)fluoranthene		<1	mg/kg	<0.1	
Phthalates	CEN ISO TS 16181 : 2011				Pass
BBP . Butyl benzyl phthalate		<1000	mg/kg	<25	
DBP . Di-butyl phthalate		<1000	mg/kg	<25	
DEHP . Di-(2-ethylhexyl) phthalate		<1000	mg/kg	<25	
DIBP . Di-isobutyl phthalate		<1000	mg/kg	<25	
(+) XRF screening	ASTM F2617 – 15				Pass
Cd (Cadmium)		<100	ppm	<100	
XRF screening (Tin)	ASTM F2617 – 15				Pass
Sn (Tin)		<150	ppm	<150	

END OF TEST REPORT

- ▲: The test was carried out by external accredited laboratory under their accreditation scope.
- : The test was carried out by external accredited laboratory, not within their accreditation scope.

Table of Performance Level for Glove

Test Item	Performance Level					
	0 ^{##}	1	2	3	4	5
Finger dexterity (EN ISO 21420) Smallest diameter of pin fulfilling test conditions (mm)	—	11.0	9.5	8.0	6.5	5.0

Performance level 0 means the glove falls below the minimum performance level for the given Individual hazard

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Ministerie van Volksgezondheid,
Welzijn en Sport

NOTIS

Lotus NL B.V. | [Log out](#)

- > My cases
- > Notify medical devices
- > Change products
- > Apply for certificate of free sale
- > Find products

Notify Class I medical devices

General data

NOTIS number	20204652
Date of receipt	9/23/2020
Status	Finalised
Date finalised	9/25/2020

Client details

Name	Lotus NL B.V.
Contact person concerning this notification	Wei, dhr. X.

Manufacturer details

Authorised representative of manufacturer	Guangdong Guyun Medical Technology Co., Ltd
Address	Three Gorges resettlement group, jigongkeng village, Futian Town, BOLUO County
Zipcode	516131
City	HuiZhou,GuangDong
Country	CHINA

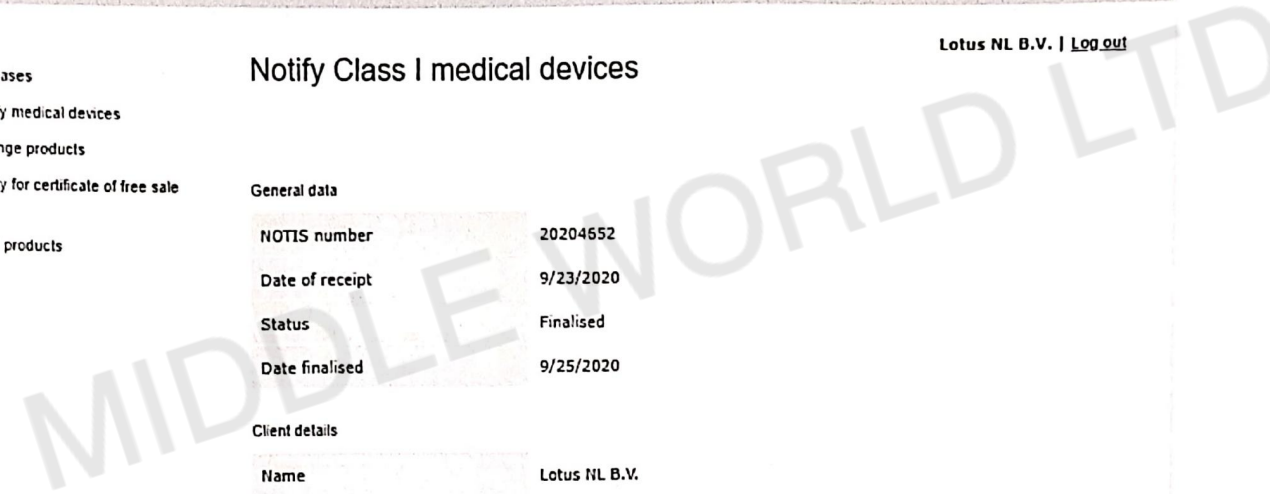
Products

Brand name	Group name	Article number(s)	Model(s)	Class	Status
-					
	<u>Disposable medical ni...</u>			MDR I	BEV

Documents

Date	File	Title
9/25/2020	20204652-0004.pdf	MDR Klasse I Bevestiging AR 1 product
9/25/2020	20204652-0005.pdf	20204652
9/23/2020	20204652-0002.pdf	Product information
9/23/2020	20204652-0001.pdf	Declaration of Conformity

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中国认可
国际互认
检测
TESTING
CNAS L3068

检测报告

报告编号: CTT2009012194CN

第 1 页 共 3 页

申请单位: 广东固云医疗科技有限公司
地 址: 中国广东省惠州市博罗县福田镇鸡公坑村三峡移民小组

收样日期: 2020 年 09 月 04 日
完成日期: 2020 年 09 月 09 日
报告日期: 2020 年 09 月 16 日

以下检测样品信息是由申请者所提供及确认:

样品名称: 一次性丁腈手套

检测结果: 请参见下页。

检测要求和结论:

序号	标准和要求	结论
1	GB 4806.11-2016 食品安全国家标准 食品接触用橡胶材料及制品 - 感官要求 - 重金属 (以铅计) - 高锰酸钾消耗量	合格

编制:

陈育梅

审核:

魏魏

授权签字人:
中鼎检测机构

何晓莹

何晓莹
技术经理



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东莞市中鼎检测技术有限公司

广东省东莞市松山湖高新技术产业开发区工业北四路 7 号

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检测报告

报告编号: CTT2009012194CN

第 2 页 共 3 页

检测结果:

感官要求 - GB 4806.11-2016: 食品安全国家标准 食品接触用橡胶材料及制品

方法: GB 4806.11-2016

材料编号	测试项目	要求	结果	单项判定
001	感官	色泽正常, 无异臭、污物。	色泽正常, 无异臭、污物	合格
	浸泡液	迁移试验所得浸泡液不应有着色、浑浊、沉淀、异臭等感官性的劣变。	迁移试验所得浸泡液无着色、浑浊、沉淀、异臭等感官性的劣变。	合格

检测结果:

重金属 (以铅计) - GB 4806.11-2016: 食品安全国家标准 食品接触用橡胶材料及制品

方法: GB 31604.9-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
001	重金属 (以铅计)	1	1	N.D.	合格

注释:

- 1、mg/kg = 毫克每千克(ppm)。
- 2、N.D. = 未检测到(小于报告限值)。
- 3、测试条件: 4% 乙酸(v/v), 60°C, 0.5h。

检测结果:

高锰酸钾消耗量 - GB 4806.11-2016: 食品安全国家标准 食品接触用橡胶材料及制品

方法: GB 31604.2-2016

材料编号	检测项目	报告限值 (mg/kg)	限值 (mg/kg)	结果 (mg/kg)	单项判定
001	高锰酸钾消耗量	1	10	N.D.	合格

注释:

- 1、mg/kg = 毫克每千克(ppm)。
- 2、N.D. = 未检测到(小于报告限值)。
- 3、测试条件: 蒸馏水, 60°C, 0.5h。

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检测报告

报告编号: CTT2009012194CN

第 3 页 共 3 页

测试材料清单

材料编号	样品描述	位置
001	蓝色橡胶	手套整体

备注: 此报告参考报告编号为 CTT2009010622CN 的数据。

样品照片:



报告完

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CNAS L3068

Test Report

Report No.: CTT2009012194EN

Page 1 of 3

Applicant: GUANGDONG GUYUN MEDICAL TECHNOLOGY CO., LTD.

Address: THREE GORGES RESETTLEMENT GROUP, JIGONGKENG VILLAGE, FUTIAN TOWN,
BOLUO COUNTY, HUIZHOU CITY, GUANGDONG PROVINCE, CHINA

Sample Received Date: Sep. 04, 2020

Completed Date: Sep. 09, 2020

Report Date: Sep. 16, 2020

The following merchandise was (were) submitted and identified on behalf of the applicant as:

Sample Name: Disposable nitrile gloves

Test Result(s): Please refer to next page(s).

Test Requested and Conclusion(s):

No.	Standard and Requirement	Conclusion(s)
1	GB 4806.11-2016 National food safety standard rubber materials and products for food contact - Sensory requirements - Heavy metal (express as Pb) - Potassium permanganate consumption	PASS

Organization:

Yumei.Chen

To examine:

Tony

Signed for and on Behalf of CTT:

Hilary He

Hilary He
Technical Manager



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Dongguan Consumer Testing
Technology Co., Ltd.

No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
Website: <http://www.cttlab.com> Email: enquiry@cttlab.com





Test Report

Report No.: CTT2009012194EN

Page 2 of 3

Test Result(s):

Sensory requirements - GB 4806.11-2016: National Food Safety Standard Food contact rubber articles

Method: GB 4806.11-2016

Material No.	Requirement	Result	Conclusion
001	Color of outlook is normal, no foreign smell, no foreign matter.	Color of outlook is normal, no foreign smell, no foreign matter.	PASS
	Migration of solution should clear, no bad smell, no foreign smell	Migration of solution clear, no bad smell, no foreign smell	PASS

Test Result(s):

Heavy metal (express as Pb) - GB 4806.11-2016: National Food Safety Standard Food contact rubber articles

Method: GB 31604.9-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
001	Heavy metal (express as Pb)	1	1	N.D.	PASS

- NOTE:**
1. mg/kg = milligram per kilogram (ppm).
 2. N.D. = Not Detected (Less than Reporting Limit).
 3. Test condition: 4% Acetic acid(v/v), 60°C, 0.5 hour.

Test Result(s):

Potassium permanganate consumption - GB 4806.11-2016: National Food Safety Standard Food contact rubber articles

Method: GB 31604.2-2016

Material No.	Test Item	Reporting Limit (mg/kg)	Limit (mg/kg)	Result (mg/kg)	Conclusion
001	Potassium permanganate consumption	1	10	N.D.	PASS

- NOTE:**
1. mg/kg = milligram per kilogram (ppm).
 2. N.D. = Not Detected (Less than Reporting Limit).
 3. Test condition: distilled water, 60°C, 0.5 hour.

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Website: <http://www.cttlab.com> Email: enquiry@cttlab.com



Test Report

Report No.: CTT2009012194EN

Page 3 of 3

Test Material List

Material No.	Sample Description	Location
001	Bluc rubber	Gloves individual

Remark: The data of this report are referred to data of CTT2009010622EN.

Photo of Sample:



End of Report

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Dongguan Consumer Testing Technology Co., Ltd.

No.7, Gongye Beisi Road, Songshanhu High-Tech Industrial Development Park, Dongguan, Guangdong, China.
 Tel: 86-0769-8898 9888 Fax: 86-0769-8898 8808 Hot Line: 400 6789 666
 Website: <http://www.cttlab.com> Email: enquiry@cttlab.com



INSTRUCTION FOR USE

Guangdong Guyun Medical Technology Co., Ltd.

Three Gorges resettlement group, jigongkeng village, Futian Town, BOLUO County, Huizhou City, Guangdong Province

China

Glove reference : Gug0101

Article code: /

User notice index : 01

Last update : DECEMBER, 2020

Glove description :

Disposable Nitrile gloves

This is a Personal Protective Equipment belonging to the category II.

It meets the requirements of the PPE Regulation 2016/425 applicable from April 21th, 2018 : innocuousness, comfort, solidity.

It has been subject to a UE-type Examination performed by :

C.T.C. (0075)

4, rue Hermann Frenkel

69367 LYON Cedex 07

FRANCE

Applicable standards :

The glove meets the requirements of the standard EN ISO 21420 : 2020 « Protective Gloves - General requirements and test methods ».

Dexterity: 5

Available Size Range: 6/S-9/XL

A different hand sizing system from the one defined in EN ISO 21420 Annex B is used:

Hand size	Hand circumference (mm)	Hand length (mm)
6/S	85	165
7/M	95	172
8/L	105	185
9/XL	115	193

Moreover, this glove has been designed for the following applications :

« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.

« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

Application :

Microorganism - EN ISO 374-5:2016



Read carefully the instructions for use provided with the product



Microorganism resistant	Conform
-------------------------	---------

Protection limit :

Users should be warned that gloves should not be worn when there is a risk of entanglement by moving parts of machines.
This model does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health.
The protection against risks or hazards which are not mentioned in this document is not warranted.
The levels of performance mentioned are only valid for the palm of the glove.
These levels of performance are obtained from the tests done according to conditions defined by the applicable standards.
The levels of performance mentioned are only valid for new gloves, not washed, nor regenerated.
Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, ...).
No flame protection is claimed. This glove shall not be in contact with naked flame.
The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.
The glove shall be used in following conditions :

Work place or similar :

- Work in food production plants
- Work in agriculture.
- Work activities where there is contact with animals and/or products of animal origin.
- Work in healthcare, including isolation and post-mortem units.
- Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
- Work in refuse disposal plants
- Work in sewage purification installations

The activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent.

Uncontrolled against viruses

Storage and cleaning notice

Keep in its original packaging, under ordinary temperature and humidity conditions and in clean, covered and ventilated premises.
The gloves are not washable.

PPE subject to ageing :

Peremption period : 2 years when stored in appropriate conditions (humidity, temperature, clean , ventilated, light). Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, ...).

Declaration of conformity :

Available with product.



CIRIS

C&K
C&K Testing

Test Report

Report No.: TS20091304R1



Verify authenticity



Guangdong Guyun Medical Technology Co.,

Applicant

Ltd

Address

Three Gorges resettlement group, jigongkeng
village, Futian Town, BOLUO County, Huizhou
City, Guangdong Province, China

Report Date

2020-10-09

Hangzhou C&K Testing Technic Co., Ltd.



Hangzhou C&K Testing Technic Co., Ltd

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Lab Add: 1/F No.4 Building and 4/F No.3 Building, Huaye Hi-Tech Industrial Park, No.1180, Bin'an Road, Binjiang District, Hangzhou 310052, China
Hotline: 4006-721-723 Tel: +86 571-8720 6535 Fax: +86 571-8990 0719 E-mail: test@ciris-group.com Website: www.ciris-ck.com



Test Report

Applicant	Guangdong Guyun Medical Technology Co., Ltd
Address	Three Gorges resettlement group, jigongkeng village, Futian Town, BOLUO County, Huizhou City, Guangdong Province, China
Sample Name	Disposable Nitrile gloves
Type/ Model	S model Gug0101
Material/ Colour	NBR
Other Info.	/
Sample Received Date	2020-09-23
Test Period	2020-09-23~ 2020-09-29

Foreseeable Food-Contact Type	All foods type
Use Conditions	Disposable,non-microwave
Use S/V	/
Test Requirement(s)	COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, and its amendment. German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB) (Section 30 and 31)
Test Item(s)	See Test Result(s)
Test Method(s)	See Test Result(s)
Test Result(s)	See Test Result(s)
Conclusion	Based on the performed tests on submitted sample(s), test result(s) comply with the regulatory requirements.
Remark	1.This report is the revision of TS20091304, the original test report is invalid.

TESTI
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ON

Prepared by: Meng Qi

Reviewed by: Li Xuefeng

Accredited Signatory by: Li Changhai

Meng Qi

Li Xuefeng

Li Changhai

Issue date: 2020-10-09

Hangzhou C&K Testing Technic Co., Ltd

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Lab Add:1/F No.4 Building and 4/F No.3 Building, Huaye Hi-Tech Industrial Park, No.1180, Bin'an Road, Binjiang District, Hangzhou 310052, China

Hotline:4006-721-723 Tel:+86 571-8720 6535 Fax:+86 571-8990 0719 E-mail:test@cirs-group.com Website:www.cirs-ck.com



Test Component(s):

No.	Sample Serial No.	Test Component(s)	Type/Model	Material/Colour	Other Info.
001	TS20091304001	Disposable Nitrile gloves	/	/	/

Photo(s):



TS20091304001

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Test Result(s):

No.	Test Item(s)	Test method	Requirement	Test Result(s)	Conclusion	
001	Migration of aromatic primary amine 3% Acetic Acid, 40°C, 2h (mg/kg)	EN 13130-1: 2004 EN ISO 14362-1-2017: 9.4-9.5	Not detected	Not detected (<0.01)	Pass	
	Sensory	Taste	DIN 10955:2004	≤2.5	0	Pass
		Smell	DIN 10955:2004	≤2.5	0	Pass
	Migration of formaldehyde 3% Acetic Acid, 40°C, 2h (mg/kg)	DD CEN/TS 13130-23:2005	≤15	<1.5	Pass	

Remark:

1. Tested by total immersion.
2. Soaking ratio is 60 cm²/100mL.
3. The migration conditions are tested as required by the customer.

Statement:

- I This report is invalid without the signature of accredited signatory. Any alteration to this report is also invalid.
- II This report is invalid without the special seal of inspection & testing and across-page seal.
- III This report shall not be part copy without written approval of Hangzhou C&K Testing Technic Co., Ltd..
- IV Any commercial activity such as advertising or propaganda is not allowed without authorization of Hangzhou C&K Testing Technic Co., Ltd..
- V The test results shown in this report refer only to the sample submitted by applicant.
- VI Please respond to Hangzhou C&K Testing Technic Co., Ltd. within fifteen working days upon receipt of this report if there is any objection.
- VII Hangzhou C&K Testing Technic Co., Ltd. guarantee that we shall not disclose information such as the commercial information, technical documents or test report to any third party.
- VIII The applicant should undertake the legal responsibility that result from providing untruth information.
- IX This report is not prove to society without the seal of China Metrology Accreditation, only for quality control.

The end of report

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Guangdong Guyun Medical Technology Co., Ltd.

**MANUFACTURER'S TECHNICAL FILE TO THE
PPE REGULATION 2016/425**

Reference of the product	:	Gug0101
Article code	:	/
Technical file index	:	01
Last update	:	DECEMBER, 2020

IDENTIFICATION

Reference of the product : : Gug0101
Article code : : /
Basic Model
Technical file index : : 01
Last update : : DECEMBER, 2020

Manufacturer :

Guangdong Guyun Medical Technology Co., Ltd.

Three Gorges resettlement group, jigongkeng village, Futian Town, BOLUO County,

Huizhou City, Guangdong Province

China

tel : 13828842059

fax :

Factory :

Guangdong Guyun Medical Technology Co., Ltd.

Three Gorges resettlement group, jigongkeng village, Futian Town, BOLUO County,

Huizhou City, Guangdong Province

China

tel: 13828842059

fax:

GLOVE DESCRIPTION

General glove description :

Disposable Nitrile gloves

This glove is designed against microorganisms risks .

This glove is intended to activity that does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent

Type of coating finish: no coating

Visual description (picture back and palm sides) :



Risk assessment (Essential Health and Safety Requirement. Annex II - PPE Regulation)			
		Applicable	Covered by
§1	Requirements defined in the Annex II §1 are applicable to all PPE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§1.4	Manufacturer's instructions and information is available	<input checked="" type="checkbox"/>	<input type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input type="checkbox"/> Marking
§2.4	If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.	<input checked="" type="checkbox"/>	<input type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking
§2.5	PPE which may be caught up during use	<input checked="" type="checkbox"/>	<input type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input type="checkbox"/> Marking
§2.12	PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Standard <input checked="" type="checkbox"/> Instruction for use <input checked="" type="checkbox"/> Marking

Glove constitution :

	Reference	Color	Material	Surfacic mass	Gauges	Thickness
Palm		blue	Nitrile			1.00mm
Back		blue	Nitrile			1.00mm
Cuff		blue	Nitrile			1.00mm

PROTECTION SCOPE

This glove meets the essential requirements of the Personal Protective Equipment Regulation 2016/425.

This glove is designed against microorganisms risks .

It is a category II product.

GENERAL REQUIREMENTS

Standard EN ISO 21420:2020

Dexterity : 5

Available size range: 6/S-9/XL

A different hand sizing system from the one defined in EN ISO 21420 Annex B table B.1 is used:

Hand size	Hand circumference (mm)	Hand length (mm)
6/S	85	165
7/M	95	172
8/L	105	185
9/XL	115	193

SPECIFIC REQUIREMENTS AND PERFORMANCE LEVELS

« X » indicates that the glove has not been submitted to the test or the test method appears not to be suitable for the glove design or material.

« 0 » indicates that the glove falls below the minimum performance level for the individual hazard.

Microorganism EN ISO 374-5:2016

This glove protect against microorganism.

The glove shall be used in following conditions :

Work place or similar :

- Work in food production plants
- Work in agriculture.
- Work activities where there is contact with animals and/or products of animal origin.
- Work in healthcare, including isolation and post-mortem units.
- Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
- Work in refuse disposal plants
- Work in sewage purification installations

The activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent

Uncontrolled against viruses.

TEST REPORTS

Laboratory	CTC	Other
EN ISO 21420 + innocuousness	S200909121_1 S200909118_1(dmfu)	
EN ISO 374-5	S200909121_1	

PPE subject to ageing :

Peremption period : 2 years when stored in appropriate conditions (humidity, temperature, clean , ventilated, light). Before use, the glove shall be visually controlled, in case of deterioration the gloves must be scrapped (abrasion, cut, tear, ...).

Cleaning:

The gloves are not washable.

MEANS OF CONTROL

1. According to certain chemical standard, we test and check the raw material before we accept them from our supplier, we keep the material at proper place and condition, marked available date and code of supplier.
2. Mainly we check the raw material for every batch. We put them at the certain place in warehouse.
3. For packing precessing, every step check the last step, signing the name of the last one.
4. We do a simple and tested by a competent laboratory CTC Shanghai as per Air leak & Water leak testing every one month. If the test result compliance with the relevant standards and reach to our requirement, we will produce mass production same as the samples, and check at least 2% of total quantity before shipment.



Test Report

No.: QDHL2010010435MD

Date: OCT.12,2020

Page: 1 of 5

GUANGDONG GUYUN MEDICAL TECHNOLOGY CO., LTD
THREE GORGES RESETTLEMENT GROUP, JIGONGKENG
VILLAGE, FUTIAN TOWN, BOLUO COUNTY, HUIZHOU CITY, GUANGDONG PROVINCE, CHINA

THE TEST RESULTS WERE TRANSFERRED FROM TEST REPORT NO. QDHL2006005323MD.
DATE: JUL.02,2020

Sample Description	:	DISPOSABLE MEDICAL NITRILE EXAMINATION GLOVES
Style/Item No.	:	GUG0101A
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	500PCS
Sample Receiving Date	:	JUN.11,2020
Final Sample Submission Date	:	JUL.01,2020
Test Performing Date	:	JUN.11,2020 TO JUL.02,2020

Test Requested

Result

- | | |
|--|------|
| 1. BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1) | Pass |
| 2. BS EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3) | Pass |
| 3. BS EN 455-3:2015 Medical Gloves for Single Use—Part 3: Requirements and Testing for Biological Evaluation (Clause 4.4, 4.6) | Pass |

Remark: -Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

Jessica Gao

Jessica Gao
Approved Signatory

scan to see the report



QDHL2010010435MD



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Test Report

No.: QDHL2010010435MD

Date: OCT.12,2020

Page: 2 of 5

Test Conducted:

1. BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes

Number of test sample	:	200 Pieces
Sample size	:	S
Number of non-conforming gloves	:	0

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note	:	1	Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:0. The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.
------	---	---	--

2. BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves b)
Size	:	Examination/procedure gloves: S

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)



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e sgs.china@sgs.com

Result 1: Dimensions

Size No.	S	
	Length (mm)	Width (mm)
1	241	84
2	238	84
3	241	83
4	237	84
5	240	83
6	241	83
7	241	84
8	245	83
9	240	84
10	244	84
11	237	85
12	239	84
13	237	83
Standard requirement	≥240	80±10
Median value	240	84

Result 2: Strength

Size: S			
Force at break (N)			
No.	Before aging	No.	After aging
	/		/
1	8.6	1	7.1
2	9.6	2	9.3
3	10.1	3	8.9
4	8.6	4	6.2
5	9.9	5	8.6
6	8.2	6	8.0
7	8.5	7	6.3
8	8.0	8	6.1
9	9.9	9	9.1
10	7.6	10	6.4
11	8.3	11	8.2
12	5.7	12	4.4
13	8.8	13	7.2
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	8.6	Median value	7.2



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Test Report

No.: QDHL2010010435MD

Date: OCT.12,2020

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3. BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

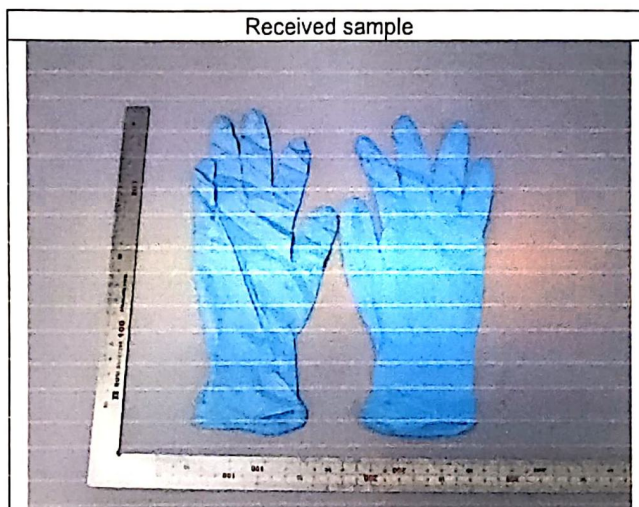
Number of test sample	:	5 Pieces
Sample size	:	S
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves

Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)
4.6	Labelling	Pass

Note	:	1	Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.16mg. (Requirement: ≤2mg per powder-free glove)
------	---	---	--

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:



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MIDDLE WORLD[®]





Trung Ha Industrial Park, Tam Nong District, Phu Tho Province: Area of 81,1 Hanoi

Middleworld company has been establishing for more than ten years. It is a reputable company in communication and event Organiser on a large scale and achieved many Awards during its operation. The world always does charity activities and contributes to the community.

Therefore, Middleworld has stepped up efforts to contribute to society to repel covid-19 transmission from The community Middleworld has invested heavily in medical equipment and PPE Production to supply medical equipment shortage at the moment promptly.

These activities have created world trust in the community and created The World Brand today.



2020 BUSINESS AWARDS



VIETNAM & THAILAND TOP BRAND

Middleworld's leadership team is experienced and discerning people, bringing The world to the top position of a fast-growing and reputable Company.

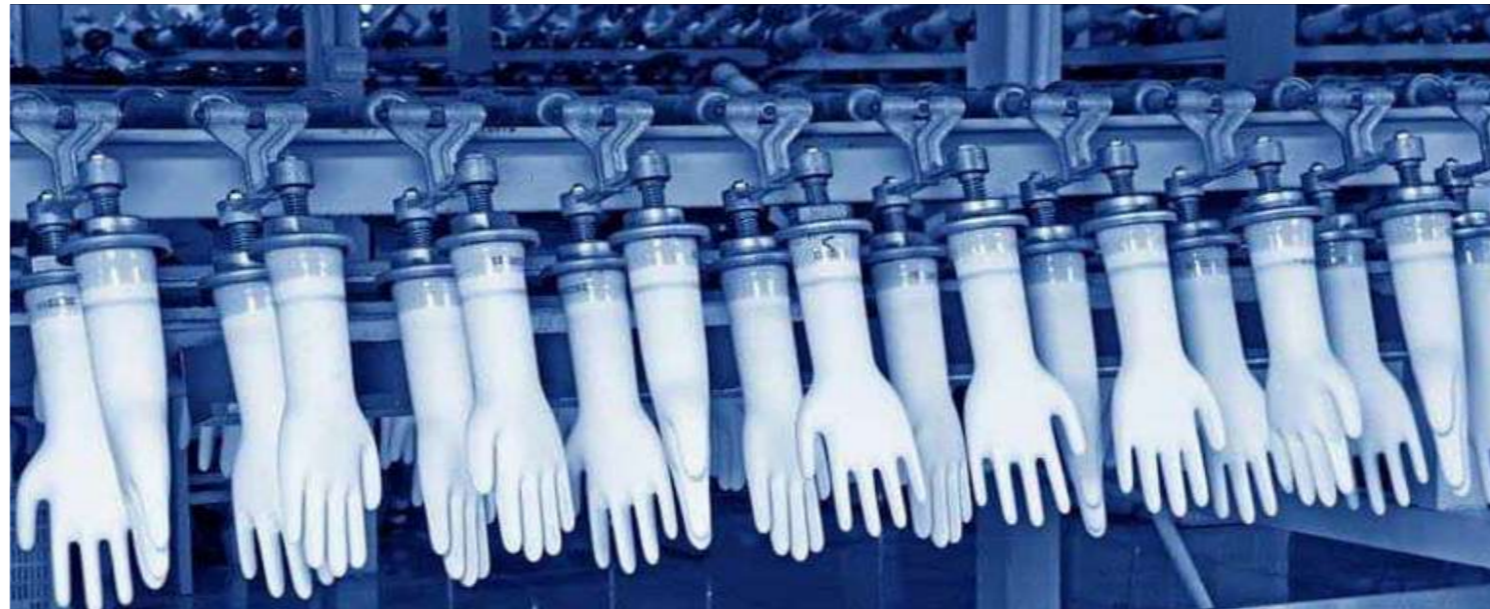
Middleworld continuously won valuable awards For their brand name in recent years, The World has been on the strong growth momentum. It has large-scale projects to become one of the country's largest PPE and disposable Nitrile Examination Glove manufacturer.



MIDDLE WORLD®

BUSINESS HIGHLIGHT

The global industrial gloves market was valued at \$6.9 billion in 2019, and is projected to reach \$14.8 billion by 2027, growing at a CAGR of 10.4% from 2020 to 2027.



The pharmaceutical industry is expected to boom significantly during the COVID-19 pandemic as huge investments have been made by the governments of both developed and developing countries to develop vaccines for COVID-19. This is also expected to surge the demand for disposable gloves to be used while manufacturing of medicines to avoid cross contamination, and to be used by the researchers working on developing the vaccines.



OUR FACTORY



MIDDLE WORLD®

OUR VISION

Global Disposable Nitrile Inspection Gloves Market is estimated to reach 17.5 Billion USD in 2020 and projected to grow at the CAGR of 10.4% during 2020-2026. According to the latest report added to the online repository of Alexareports the Disposable Nitrile Inspection Gloves market has witnessed an unprecedented growth till 2020. The extrapolated future growth is expected to continue at higher rates by 2026

#3 KEY POINT FOR GLOVE INDUSTRY TO GROWTH

1

With hand hygiene being considered as one of the most important contributing factors in food poisoning incidents, gloves play an important role in many food handling processes and are a vital tool in controlling food safety risk

2

Gloves can provide an important physical barrier between a food handler and the food to be consumed. By extension, they serve to protect the food business, its customers and its reputation. That alone should make product selection an important purchasing decision.

3

Medical gloves are disposable or reusable gloves used during medical examination, cleaning, and surgical procedures to help prevent cross-contamination between caregivers and patients. These gloves are made from different types of polymer including nitrile rubber, latex, vinyl, and neoprene. Medical gloves are available in powdered or in non-powdered form.



PROJECT TIMELINE

- Total project production capacity of 430 lines: $430,000 \text{ cartons/day} * 30 \text{ days} = 12,900,000 \text{ cartons/month}$ 12 months = 158,400,000 cartons/year
- Expected payment to the state budget: The completed project will contribute to the budget of Phu Tho province from 5,000 billion VND
- The main consumer market is the US; Japan; Korea and EU Expected average revenue per year
- After completing the factory (based on total 430 production lines of gloves): 200,000 billion VND

Total investment is estimated :
31.680 billion VND = 1,366,117,146.00 USD

Estimated contribution to the state budget: the completed project will contribute to the budget of Phu Tho province from 400-600 billion VND/year.

The Total project production capacity of 430 lines: $430,000 \text{ cartons/day} * 30 \text{ days} = 12,900,000 \text{ cartons/month} * 12 \text{ months} = 158,400,000 \text{ cartons/year}$ The main consumer market is the US; Japan; Korea and EU

STAGE 1

Financial statements are expected 3 years after the factory is completed with 10 glove production lines starting from the first quarter of 2021.

STAGE 2

TOTAL Of 40 Production line *
 $1,000 \text{ BOX / UNIT} = 20,000 \text{ BOXES} *$
 $30 \text{ DAYS} = 600,000 \text{ BOX / MONTH}$

STAGE 3

TOTAL Of 395 Production line *
 $1,000 \text{ BOX / UNIT} = 395,000 / \text{BOX} * 30 \text{ DAYS} = 11,850,000 \text{ BOX / MONTH}$



**Expected average revenue per year after completion the factory
(based on total 430 production lines of gloves): ~ 200,000 billion VND**



The Medical Gloves Market is expected to grow at a robust rate during the forecast period. The Medical Gloves market is driven by the increasing prevalence of this disease across different parts of the globe. This has increased the need to protect the world from the virus,



MIDDLE WORLD®

OUR PROJECT

1-Select wastewater treatment technologies based on advanced technologies combining biological and chemical treatment and automation, stable operation, and high treatment efficiency. Using,



2-stage flocculation technology and combining biological treatment method by activated sludge process.

3-Equipment for wastewater treatment plants is provided synchronously, mainly imported from Japan, G7, Italy, USA and some auxiliary equipment purchased domestically.



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