Guantes Nitrilo sin polvo color azul con certificación 374-5

(caja 100 unidades)

Características técnicas:

- **Material: Nitrilo**
- **Color: Azul**
- **Alargamiento máximo: 450%.**
- **Resistencia a la tracción: 16 MPA**
- **Tallas: S - M - L - XL**
- **Guantes elaborados en material no estéril**
- **Es conforme a: Los requisitos de las Normas EN420:2003+A1:2009, EN ISO 374-1:2016, EN ISO 374-5:2016, EN374-4:2013**

- **Según los Test Report:**

- **CHT02272948/1828, CHT027061371819/issue 3, CHT0269921/1816/EN/A**
- **CHT0269921/1816/EN/B/, CHT0269921/1816/JS/C**

- **Para los siguientes productos:**

- **Hidróxido de sodio(K) 40%, Nivel 6 >480 min.**
- **Ácido sulfúrico(L) 96%, Nivel 1 >10 min.**
- **Emitidos por el Organismo Notificado N.o 2777 SATRA Technology Europe Limited Bracetown Business Park Clonee, D15YN2P, Republic of Ireland Según el Reglamento 2016/425 y por lo tanto clasificado como EPI CE CAT III**

Calle Sierra Filabres 1. Polígono Industrial La Olivilla.
CP:28946. Fuenlabrada (Madrid).

91 632 77 40

tienda@fisaude.com

498/188 Sammakorn Avenue. Ramindra, Ta Raeng, Bangkhen District, Bangkok 10220 Thailand Tel: +662 103-1680 Email: info@hnmedicalgroup.com

EU DECLARATION OF COMFORMITY

We, HN MEDICAL GROUP Company Limited
& MEDYBIRD LIMITED

Head Office Address:
HN MEDICAL GROUP Co.,Ltd.
498/188 Sammakorn Avenue. Ramindra, Ta Raeng,
Bangkhen District. Bangkok, 10220 Thailand

MEDYBIRD Ltd
51 Bracken Road, Sandyford, Dublin 18 CV48, Ireland

Hereby declare that the following product, meet the provisions of

PPE Regulation (EU) 2016/425 (Module C2) for Category III as following;

Manufacturing Plant: HN Medical Group Company Limited (Thailand)
99/9 Moo 16 Nongheang, Panusnikom, Chonburi 20140 Thailand

EU Representative / Distribution Partner : MEDYBIRD LIMITED

Application Standard(s)
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016.

Product Description

Brand Name	Product	Size	Product Sold
M+D Disposable NItrile Gloves Kleans Disposable Nitrile Gloves EXCEL Disposable Nitrile Gloves MEDYBIRD NITRILE Disposable Gloves	Acrylonitrile Butadiene Rubber Powder-free Disposable Gloves, (Non-Sterile)	M (7-8); L (8-9);	HN202001 HN202002 HN202003 MD202007

This declaration applies to all products manufactured identical to submitted for testing and assessment of compliance of the product with the requirement relating to safety standards listed above was performed by manufacturer HN Medical Group Co.,Ltd. and EU/REP MEDYBIRD LIMITED. The conformity to type based on quality assurance of the production process under surveillance of the EU Type Examination Certificate Number: **2777/15635-01/E00-00** by SATRA Technology Euroup Limited Notified Body: 2777. Bracetown Business Park. Clonee. D15YN2P Republic of Ireland.

We explicitly designate MEDYBIRD LIt(Ireland) 51 Bracken Road, Sandyford, Dublin 18 CV48, Ireland . to act as our sole Authorized **EC/REP** in the European Union for the above indicated products.

Signature:

HN Medical Group Co.,Ltd.

Divari Varintip
Managing Director

Medybird ltd(Dublin)
signature

Danny Manu
Director/ceo

Issued to:

Notified Body: 2777

SATRA customer number: P20305

EU Type-Examination Certificate

Certificate number: 2777/15635-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:
Medybird MB202007
Kleanse Glove HN202002
Excel Glove HN202003
MD Glove HN202001

Description:
Five finger Blue nitrile, powder free, disposable, examination glove

Sizes:
7 & 9

Classification:

EN ISO 374-1:2016+A1:2018 Type C	**Level**	**EN ISO 374-4:2019**
Sodium hydroxide 40% (K)	6	4.5%

EN ISO 374-5:2016
Protection against bacteria and fungi – Pass
Protection against viruses – Pass

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

Technical reports/Approval documents:
SATRA: CHM0301868/2035/LH/A, CHM0301868/2035/LH/B, CHM0301868/2035/LH/C, CHM0301868/2035/SPT

Signed on behalf of SATRA: Tara Holly Quincey Brown

Date first issued: 27/01/2021
Date of issue: 27/01/2021

Expiry date: 27/01/2026

CERTIFICATES

HN MEDICAL GROUP

Product Conformance

- ✓ EN 455-1:2000- Medical gloves for single use. Requirements and testing for freedom from holes
- ✓ EN 455-2:2015- Medical gloves for single use. Requirements and testing for physical properties (Tensilestrength as received, Tensile strength after ageing and Sizing on 3 sizes)
- ✓ EN 1186-3:2002 in accordance with SATRA SOP CAT-011 Issue 1- Materials and articles in contact with foodstuffs. Plastics. Test methods for overall migration into aqueous food simulants by total immersion (Single use) against simulants A and B
- ✓ EN ISO 21171:2006- Medical gloves. Determination of removable surface powder (as required by EN 455-3:2015)
- ✓ EN 16523-1:2015+A1:2018 in accordance with SATRA SOP CAT-009- Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact against 40% Sodium hydroxide
- ✓ EN ISO 374-4:2019- Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals against 40% Sodium hydroxide
- ✓ EN ISO 3071:2020- Textiles. Determination of pH of aqueous extract
- ✓ EN ISO 374-5:2016 - ISO 16604:2004 Resistance to penetration by blood borne pathogens(bacteriophage Phi-X174) (sent to an external ISO 17025 accredited laboratory)
- ✓ EN ISO 374-2:2019- Protective gloves against dangerous chemicals and microorganisms. Determinationof resistance to penetration
- ✓ EN ISO 21420:2020- Protective gloves. General requirements and test methods-size and dexterity

AQL 1.5

SATRA TECHNOLOGY

bsi.

FDA

HN MEDICAL GROUP

COMMITMENT FOR TEST RESULT AND CERTIFICATE

Dear Valued Customers

We, HN Medical Group Co., Ltd would like to confirm our COMMITMENT for Test Result and Certificate to our valued Customers and our Exclusive Distributor.

NO.	Standards	Date	Organization	Remarks:
1	EN ISO 21420:2020 EN 16523-1:2015+A1:2018	COMPLETED	SATRA	Test Reports
2	EN ISO 374-1:2016+A1:2018 EN ISO 374-2:2019 EN ISO 374-4:2019 EN ISO 374-5:2016	COMPLETED	SATRA	Test Reports
3	PPE (EU) 2016/425	NOV-15	SATRA CE 2777 NB	EU Type Examination Certificate
4	EN1186-1/2/3:2002 (EU)10/2011 ANNEX III EN ISO 21171:2006 ~~EN455-3:2015~~ EN455-1:2000; EN455-2:2015; EN455-3:2015	COMPLETED	SATRA/TUV	SATRA Test Reports / TUV Certificate of Conformity (COC)
5	MDD (EU) 93/42/EEC	NOV-25	BSI	CE Notify Body
6	ISO 9001:2015	COMPLETED	GSCS	QMS Certificate
7	ISO 13485:2016	COMPLETED	GSCS	Medical Device QMS Certificate
8	US-FDA 21 CFR 177.2600 (RUBBER ARTICLE)	COMPLETED	TUV	Test Report
9	FDA FACILITY REGISTRATION	COMPLETED	FDA	Operator No.10077462
10	FDA DEVICE LISTING	COMPELTED	FDA	Product Code: FMC
11	FDA DEVICE CORRESPONDENT	COMPLETED	FDA	21 CFR. Regulation: 880.6250
12	FDA 510(K) SUMMARY ASTM D6319-19	DEC-25	FDA	CODE: LZA ASTM D6319-19 Survey
13	SA8000:2014	Dec-25	SAI	SAAS
14	GMP	Dec-25	Thai - FDA	National Good Manufacturing Practice Certificate

HN Medical Group Co.,Ltd.

Managing Director: Varintip Divari

HN Medical Group Co., Ltd

Your Solution of Medical Regimen

ISO 9001:2015

GSCS

GSCS International Ltd.

Certificate of Registration

This is to certify that

Quality Management System

Of

HN MEDICAL GROUP CO., LTD.

498/188 Kanchanaphisek Road, Tharang Subdistrict, Bang Khen District, Bangkok, 10220, THAILAND

for

Manufacture, Import and Export Including Purchase and Sell Locally of Nitrile, Latex and Vynyl Gloves and Rubber Products

has been assessed and registered against the provision of

ISO 9001:2015

International Standard With

Registration Number	: 20011082	Project	: GSCS-103-1034-Q
Certification Date	: 26 September, 2020	Code	: C.32.99
First Surveillance Due date	: 25 September, 2021	Exclusions	: N/A
Second Surveillance Due Date	: 25 September, 2022	Issue No	: 01
Expiry date	: 25 September, 2023		

Certification Approved By:

Managing Director

ASCB Accreditation Services Worldwide

IRQAO

Registration is subject to the management system being continually maintained to the above standard under regular surveillance. Should surveillance not take place when required, registration shall be removed.
This certificate is the property of GSCS International Ltd.
Please validate the authenticity and status of this certificate at https://gscsintl.com/certificate-check/

ISO 9001: 2015
Certificate of Registration

Quality Management System

HN MEDICAL GROUP

ISO 13485:2016

GSCS

GSCS International Ltd.

Certificate of Registration

This is to certify that

Medical Devices Quality Management System

Of

HN MEDICAL GROUP CO., LTD.

498/188 Kanchanaphisek Road, Tharang Subdistrict, Bang Khen District, Bangkok, 10220, THAILAND

for

Manufacture, Import and Export Including Purchase and Sell Locally of Nitrile, Latex and Vynyl Gloves and Rubber Products

has been assessed and registered against the provision of

ISO 13485:2016 & EN ISO 13485:2016

International Standard With

Registration Number	: 20011083	Project	: GSCS-103-1009-M
Certification Date	: 26 September, 2020	Code	: C.32.99
First Surveillance Due date	: 25 September, 2021	Exclusions	: 7.3, 7.5.3, 7.5.4, 7.5.5 ,7.5.7, 7.5.9.2
Second Surveillance Due Date	: 25 September, 2022	Issue No	: 01
Expiry date	: 25 September, 2023		

Certification Approved By:

Managing Director

ASCB Accreditation Services Worldwide

IRQAO

Registration is subject to the management system being continually maintained to the above standard under regular surveillance. Should surveillance not take place when required, registration shall be removed.
This certificate is the property of GSCS International Ltd.
Please validate the authenticity and status of this certificate at https://gscsintl.com/certificate-check/

ISO 13485: 2016 Certificate of Registration

Medical Devices Quality Quality Management System

HN MEDICAL GROUP

2020

CERTIFICATE OF REGISTRATION

This certifies that:

HN MEDICAL GROUP CO., LTD.
70/46 Soi 1 Kanchanaphisek 7, Khannayao Sub.
Khannayao District
Bangkok , TH 10230

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10077462**
Device Classification Name:	**PATIENT EXAMINATION GLOVE**
Product Code:	**FMC**
Regulation Number:	**880.6250**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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

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

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. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lemarz
Executive Director
Registrar Corp
Dated: August 31, 2020

FDA Certificate of Registration

HN MEDICAL GROUP

From: reglist@cdrh.fda.gov
Sent: Saturday, August 29, 2020 3:37 AM
To: joeyzh@live.com
Subject: Notification of New Device Establishment Registration

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave., WO66 Room 1423
Silver Spring, Maryland 20993-0002

August 28, 2020

Name of Official Correspondent **DAVID LENNARZ**
Address of Official Correspondent **144 RESEARCH DRIVE**
HAMPTON, VIRGINIA 23666
UNITED STATES
DAVID.LENNARZ@REGISTRARCORP.COM

Owner Operator Number 10077462

Dear Sir or Madam,

We have received your registration and listing information for the following medical device establishment

Establishment Name **HN MEDICAL GROUP CO., LTD.**
Establishment Address **70/46 SOI 1 KANCHANAPHISEK 7, KHANNAYAO SUB.**
KHANNAYAO DISTRICT
BANGKOK, 10230
THAILAND

The information submitted has been processed and entered into the FDA Registration and Device Listing Database. Your device establishment is now considered registered. You will be notified of your official registration number within 90 days.

Once you receive a registration number, you are required to re-register on an annual basis from October through December. Failure to re-register every year will invalidate your registration and result in your device establishment and listing information being removed from the FDA Medical Device Registration and Listing Web site.

For inquiries about the status of your registration or assignment of your registration number, please contact the Registration and Listing Program Office at reglist@cdrh.fda.gov or calling (301) 796-7400.

Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

1 result found for **Establishment Registration or Business Trade Name :** *HN Medical Group*

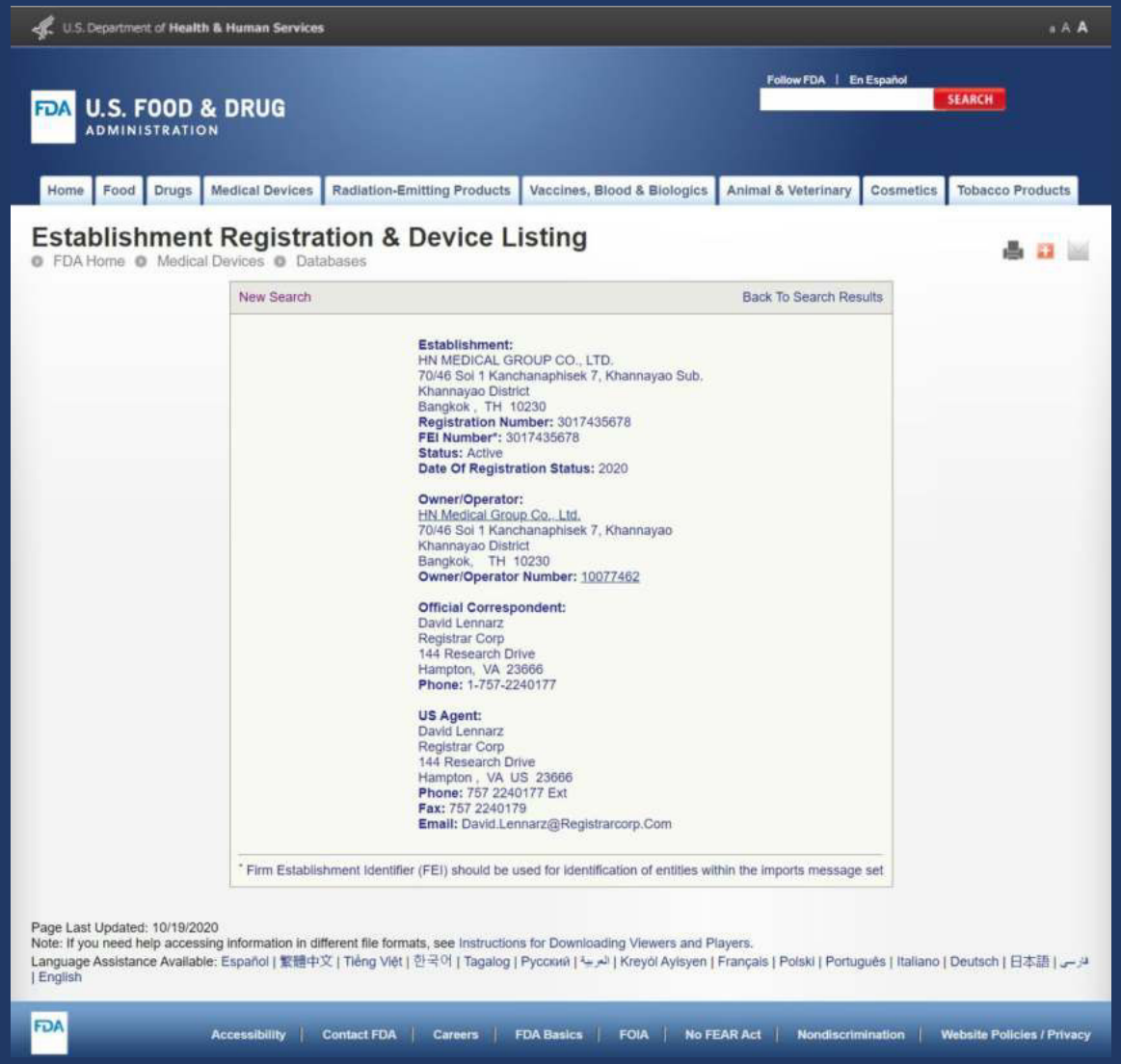
New Search

Establishment Name	Registration Number	Current Registration Yr
HN MEDICAL GROUP CO., LTD. THAILAND	3017435678	2020
• Patient Examination Glove		Foreign Exporter; Manufacturer; Remanufacturer; Repackager/Relabeler

FDA Certificate of Registration

HN MEDICAL GROUP

FDA USA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Establishment:
HN MEDICAL GROUP CO., LTD.
70/46 Soi 1 Kanchanaphisek 7, Khannayao Sub.
Khannayao District
Bangkok , TH 10230
Registration Number: 3017435678
FEI Number*: 3017435678
Status: Active
Date Of Registration Status: 2020
Owner/Operator:
HN Medical Group Co., Ltd.
70/46 Soi 1 Kanchanaphisek 7, Khannayao
Khannayao District
Bangkok, TH 10230
Owner/Operator Number: 10077462
Official Correspondent:
David Lennarz
Registrar Corp
144 Research Drive
Hampton, VA 23666
Phone: 1-757-2240177
US Agent:
David Lennarz
Registrar Corp
144 Research Drive
Hampton , VA US 23666
Phone: 757 2240177 Ext
Fax: 757 2240179
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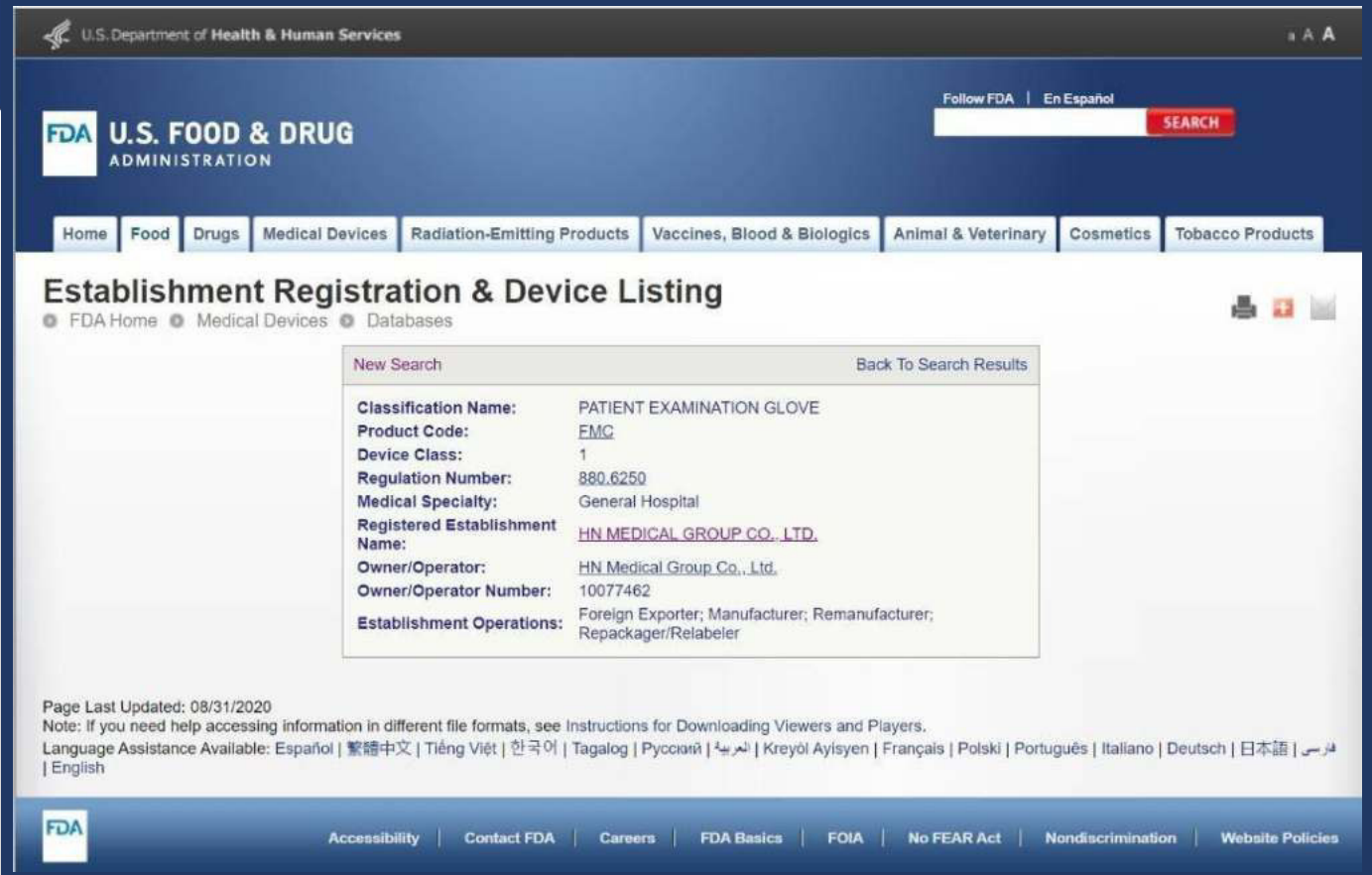
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Classification Name: PATIENT EXAMINATION GLOVE
Product Code: FMC
Device Class: 1
Regulation Number: 880.6250
Medical Specialty: General Hospital
Registered Establishment Name: HN MEDICAL GROUP CO., LTD.
Owner/Operator: HN Medical Group Co., Ltd.
Owner/Operator Number: 10077462
Establishment Operations: Foreign Exporter; Manufacturer; Remanufacturer; Repackager/Relabeler
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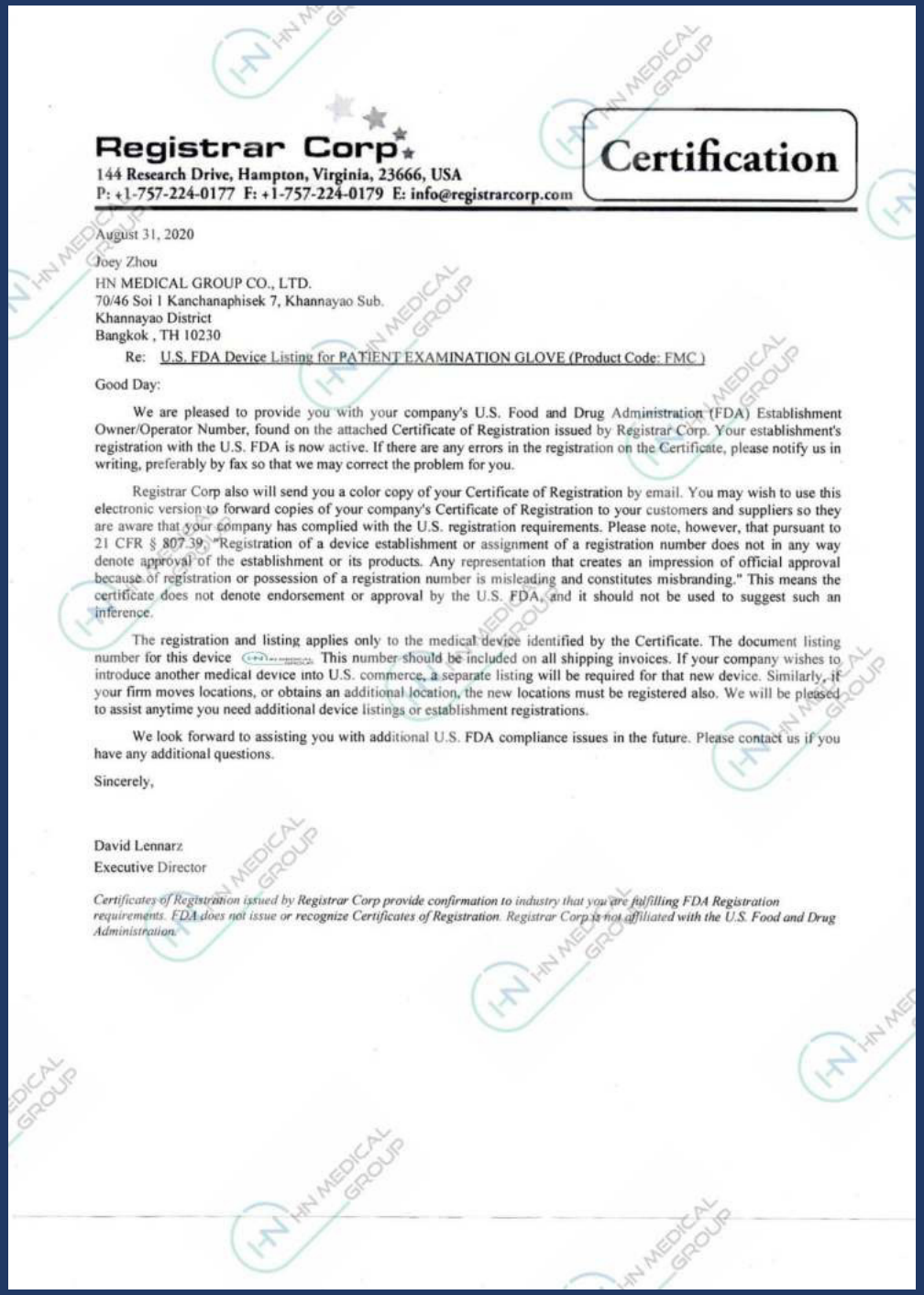

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
P: +1-757-224-0177 F: +1-757-224-0179 E: info@registrarcorp.com

Certification

August 31, 2020

Joey Zhou
HN MEDICAL GROUP CO., LTD.
70/46 Soi 1 Kanchanaphisek 7, Khannayao Sub.
Khannayao District
Bangkok , TH 10230

Re: U.S. FDA Device Listing for PATIENT EXAMINATION GLOVE (Product Code: FMC)

Good Day:

We are pleased to provide you with your company's U.S. Food and Drug Administration (FDA) Establishment Owner/Operator Number, found on the attached Certificate of Registration issued by Registrar Corp. Your establishment's registration with the U.S. FDA is now active. If there are any errors in the registration on the Certificate, please notify us in writing, preferably by fax so that we may correct the problem for you.

Registrar Corp also will send you a color copy of your Certificate of Registration by email. You may wish to use this electronic version to forward copies of your company's Certificate of Registration to your customers and suppliers so they are aware that your company has complied with the U.S. registration requirements. Please note, however, that 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." This means the certificate does not denote endorsement or approval by the U.S. FDA, and it should not be used to suggest such an inference.

The registration and listing applies only to the medical device identified by the Certificate. The document listing number for this device [redacted]. This number should be included on all shipping invoices. If your company wishes to introduce another medical device into U.S. commerce, a separate listing will be required for that new device. Similarly, if your firm moves locations, or obtains an additional location, the new locations must be registered also. We will be pleased to assist anytime you need additional device listings or establishment registrations.

We look forward to assisting you with additional U.S. FDA compliance issues in the future. Please contact us if you have any additional questions.

Sincerely,

David Lennarz
Executive Director

Certificates of Registration issued by Registrar Corp provide confirmation to industry that you are fulfilling FDA Registration requirements. FDA does not issue or recognize Certificates of Registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

FDA Device Listing Number

HN MEDICAL GROUP

EU DECLARATION OF COMFORMITY

We, HN Medical Group Company Limited (Thailand)

Head Office Address:
498/188 Sammakorn Avenue. Ramindra, Ta Raeng,
Bangkhen District. Bangkok, 10220 Thailand

Hereby declare that the following product, meet the provisions of

PPE Regulation (EU) 2016/425 (Module D) For Category III as following;

Manufacturing Plant: **HN Medical Group Company Limited (Thailand)**
99/9 Moo 16 Nongheang, Panusnikom, Chonburi 20140 Thailand

EU Representative / Distribution Partner : **MEDYBIRD LIMITED (UK)**
2nd Floor, Bollin House, Bollin Walk, Wilmslow SK9 1DP United Kingdom

Application Standard(s)
EN ISO 21420:2020, EN ISO 374-1:2016, EN 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016 - ISO 16604:2004, PD CEN ISO/TS 16190:2013 and EN 16523-1:2015+A1:2018.

Product Description

Brand Name	Product	Size	Product Sold
M+D Disposable NItrile Gloves Kleans Disposable Nitrile Gloves EXCEL Disposable Nitrile Gloves MEDYBIRD NITRILE Disposable Gloves	Acrylonitrile Butadiene Rubber Powder-free Disposable Gloves, (Non-Sterile)	XS (5-6); S (6-7); M (7-8); L (8-9); XL (9-10)	HN202001 HN202002 HN202003 MD202007

This declaration applies to all products manufactured identical to submitted for testing and assessment of compliance of the product with the requirement relating to safety standards listed above was performed by manufacturer HN Medical Group Co.,Ltd. and EU/REP MEDYBIRD LIMITED(UK). The conformity to type based on quality assurance of the production process under surveillance of the report number **CHM0301868/2035** by SATRA Technology Centre Ltd.

We explicitly designate SATRA Technology Centre Ltd. to act as our sole Authorized Representative in the European Union for the above indicated products.

Signature:

HN Medical Group Co.,Ltd.

Divari Varintip
Managing Director

EU DECLARATION OF COMFORMITY

We, HN Medical Group Company Limited (Thailand)

Head Office Address:
498/188 Sammakorn Avenue. Ramindra, Ta Raeng, Bangkhen District. Bangkok, 10220 Thailand

Hereby declare that the following product, meet the provisions of

Medical Devices Directive (EU) 93/42/EEC for ANNEX I & III

Commission Regulation (EU) 10/2011 ANNEX II & III

Commission Regulation (EU) 2016/1416 & (EU) 2017/752

Manufacturing Site: HN Medical Group Company Limited (Thailand)

99/9 Moo 16 Nongheang, Panusnikom, Chonburi 20140 Thailand

EU Representative / Distribution Partner : MEDYBIRD LIMITED (UK)

2nd Floor, Bollin House, Bollin Walk, Wilmslow SK9 1DP United Kingdom

Application Standard(s)

EN 1186-2&3:2002, EN 455-1:2000, EN 455-2:2015, ≠EN ISO 21171:2006, ≠SATRA SOP CAT-015, ≠SATRA SOP CAT-035 and EN 455 Part 1,2,3 by TUVRheinland. ISO9001:2015 (GSCS 200110-82) and ISO13486:2016 (GSCS 200110-83)

Product Description

Brand Name	Product	Size	Product Sold
M+D Disposable Nitrile Gloves KLEANSE Disposable Nitrile Gloves EXCEL Disposable Nitrile Gloves MEDYBIRD(UK) Nitrile Disposable Gloves	Acrylonitrile Butadiene Rubber Powder-free Disposable Gloves (Non-Sterile)	XS (5-6); S (6-7); M (7-8); L (8-9); XL (9-10)	HN202001 HN202002 HN202003 MD202007

This declaration applies to all products manufactured identical to submitted for testing and assessment of compliance of the product with the requirement relating to safety standards listed above was performed by HN Medical Group Co.,Ltd. EU/REP - MEDYBIRD(UK) LIMITED. The conformity to type based on quality assurance of the production process under surveillance of the report reference number **CHM0300325/2029** by SATRA Technology Centre Ltd; and the report job number **242026551** by TUVRheinland.

We explicitly designate SATRA Technology Centre Ltd. to act as our sole Authorized Representative in the European Union for the above indicated products.

Signature:

HN Medical Group Co.,Ltd.

Divari Varintip
Managing Director

SATRA Technology Centre Ltd
Wyndham Way, Telford Way,
Kettering, Northamptonshire NN16 8SD
United Kingdom
Tel: +44(0)1536 410000 Fax: +44 (0)1536 410626
e-mail: info@satra.com

ORDER ACKNOWLEDGEMENT

HN Medical Group Co.,LTD

498/188 Sammakorm Ave.
RamindraTa Raeng,
Bangkhen District,
Bangkok 10220 Thailand

info@hnmedicalgroup.com
Tel: na

Issue Date: 30th September 2020
Issue Number: 01

Our Reference: **CHM0301868/2035**
Please quote this number when contacting SATRA
Your Reference/PO:

Thank you for your request for work as follows:

Testing in accordance with EN 374-1 on unreferenced nitrile gloves - PAID WITH THANKS - 25.09.20

- EN 16523-1:2015+A1:2018 in accordance with SATRA SOP CAT-009- Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact against 40% Sodium hydroxide

Permeation rate graphs will be reported for all chemicals. Please contact us before the estimated completion date if permeation rate graphs are not required

- EN ISO 374-4:2019- Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals against 40% Sodium hydroxide
- ≠EN ISO 3071:2020- Textiles. Determination of pH of aqueous extract
- ≠PD CEN ISO/TS 16190:2013 in accordance with SATRA SOP CAT-047- Footwear. Critical substances potentially present in footwear and footwear components. Test method to quantitatively determine polycyclic aromatic hydrocarbons (PAH) in footwear materials For 8 PAHs only (those restricted by REACH)

NOTES:
1) Unless otherwise requested at the time of order, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at your expense.
2) All testing and calibration work is conducted under our ISO 17025 quality management system or equivalent. Any individual test or calibration marked ≠ falls outside the UKAS accreditation schedule for SATRA.
3) When quoting pass/fail or performance levels we do not take uncertainty of measurement into account, but will include notes to indicate if the result could be affected by the uncertainty.
4) Testing that includes deviations requested by the customer will not be reported as a pass/fail or with a performance level as SATRA cannot confirm what effect, if any the deviation has had on the results obtained.
5) Where a proforma invoice has been raised, work will not start until payment is received in full. Payments may take several days to be received into our account.
6) Our standard terms and conditions of business shall exclusively apply to all orders; please see the attached, our website (www.satra.com) or consult your SATRA contact for further details.
7) Descriptions and or references relating to products submitted are based on visual inspection of the items and or information supplied by the customer.

For more information on the full range of services that we offer, please visit our website at www.satra.com

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United Kingdom
Tel: +44(0)1536 410000 Fax: +44 (0)1536 410626
e-mail: info@satra.com

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- ≠EN ISO 374-5:2016 - ISO 16604:2004 Resistance to penetration by blood borne pathogens (bacteriophage Phi-X174) (sent to an external ISO 17025 accredited laboratory)
- EN ISO 374-2:2019- Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration
- ≠EN ISO 21420:2020- Protective gloves. General requirements and test methods-size and dexterity

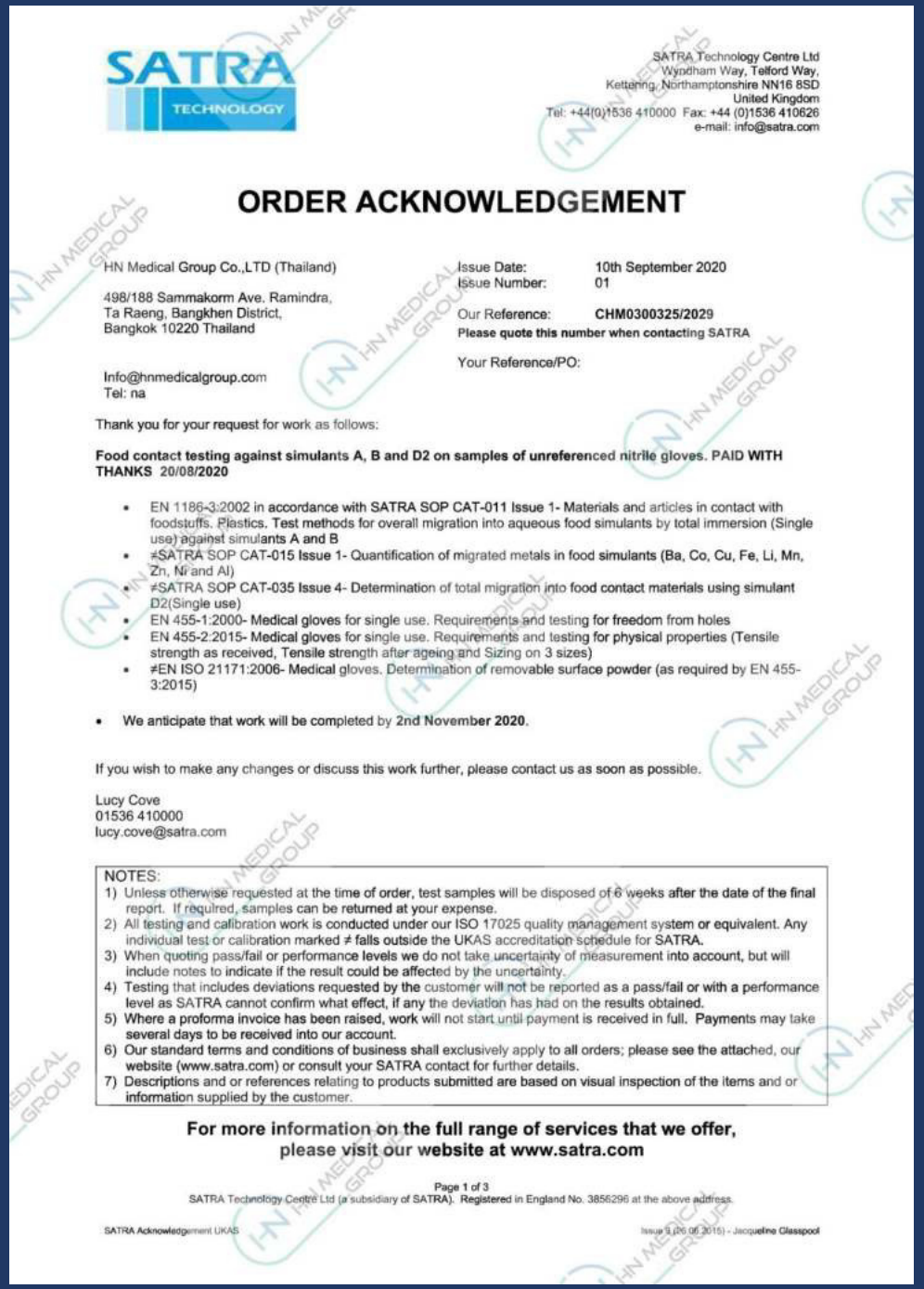
- We anticipate that work will be completed by **3rd November 2020** .

If you wish to make any changes or discuss this work further, please contact us as soon as possible.

Jade Hurley
01536 410000
Jade.hurley@satra.com

Medybird Limited «J_JOB_NUM»

ORDER ACKNOWLEDGEMENT



SATRA TECHNOLOGY

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ORDER ACKNOWLEDGEMENT

HN Medical Group Co.,LTD (Thailand)

498/188 Sammakorm Ave. Ramindra,
Ta Raeng, Bangkhen District,
Bangkok 10220 Thailand

Info@hnmedicalgroup.com
Tel: na

Issue Date: 10th September 2020
Issue Number: 01

Our Reference: **CHM0300325/2029**
Please quote this number when contacting SATRA

Your Reference/PO:

Thank you for your request for work as follows:

Food contact testing against simulants A, B and D2 on samples of unreferenced nitrile gloves. PAID WITH THANKS 20/08/2020

- EN 1186-3:2002 in accordance with SATRA SOP CAT-011 Issue 1- Materials and articles in contact with foodstuffs. Plastics. Test methods for overall migration into aqueous food simulants by total immersion (Single use) against simulants A and B
- ≠SATRA SOP CAT-015 Issue 1- Quantification of migrated metals in food simulants (Ba, Co, Cu, Fe, Li, Mn, Zn, Ni and Al)
- ≠SATRA SOP CAT-035 Issue 4- Determination of total migration into food contact materials using simulant D2(Single use)
- EN 455-1:2000- Medical gloves for single use. Requirements and testing for freedom from holes
- EN 455-2:2015- Medical gloves for single use. Requirements and testing for physical properties (Tensile strength as received, Tensile strength after ageing and Sizing on 3 sizes)
- ≠EN ISO 21171:2006- Medical gloves. Determination of removable surface powder (as required by EN 455-3:2015)

- We anticipate that work will be completed by 2nd November 2020.

If you wish to make any changes or discuss this work further, please contact us as soon as possible.

Lucy Cove
01536 410000
lucy.cove@satra.com

NOTES:
1) Unless otherwise requested at the time of order, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at your expense.
2) All testing and calibration work is conducted under our ISO 17025 quality management system or equivalent. Any individual test or calibration marked ≠ falls outside the UKAS accreditation schedule for SATRA.
3) When quoting pass/fail or performance levels we do not take uncertainty of measurement into account, but will include notes to indicate if the result could be affected by the uncertainty.
4) Testing that includes deviations requested by the customer will not be reported as a pass/fail or with a performance level as SATRA cannot confirm what effect, if any the deviation has had on the results obtained.
5) Where a proforma invoice has been raised, work will not start until payment is received in full. Payments may take several days to be received into our account.
6) Our standard terms and conditions of business shall exclusively apply to all orders; please see the attached, our website (www.satra.com) or consult your SATRA contact for further details.
7) Descriptions and or references relating to products submitted are based on visual inspection of the items and or information supplied by the customer.

For more information on the full range of services that we offer, please visit our website at www.satra.com

ORDER ACKNOWLEDGEMENT

HN MEDICAL GROUP

Products

TÜVRheinland®
Precisely Right.

Report No.:	242123010-01	Page 1 of 4
Client:	HN MEDICAL GROUP CO., LTD. 498/188 Sammakorn Avenue Ramindra, Ta Raeng, Bangkhen, Bangkok 10220 Thailand	
Identification/ Model No(s):	M+D Glove Disposable Nitrile Examination Glove	
Model No(s):	HN202001	
Sample Receiving date:	2020-09-30	
Testing Period:	2020-09-30 to 2020-10-21	
Delivery condition:	*Apparent good, Samples tested as received*	

Test Specification:	*Test result:*
Test parameter was selected by client	
1. US FDA 21 CFR 177.2600 (Rubber Articles) - Determination of Amount of Extractives	PASS

Other Information:

Material type: Nitrile Glove

Grade: Examination

Manufacture: HN Medical Group Co., Ltd.

Country of Origin: Thailand

Country of Destination: US/Canada, UK, EU (Including Germany)

For and on behalf of
TÜV Rheinland Thailand Ltd.

TÜV RHEINLAND THAILAND LTD. TÜV

2020-10-27 — Wilawan Sriphrom / Manager

Date — *Name/Position*

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

TÜV Rheinland Thailand Limited. ·
123/1, Soi Chalongkrung 31, Lam Pla Thio, Lat Krabang, Bangkok 10520 Thailand
Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: info@tha.tuv.com · Web:www.tuv.com

Material list

Item: MD Glove Disposable Nitrile Examination Glove

Material No.	Material	Color	Location
M001	NITRILE	Natural White	Refer to photo
M002	NITRILE	Blue	Refer to photo

US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives

Test Method: With reference to US FDA 21 CFR 177.2600.

For use in contact with aqueous foods:

Extractants	Test Condition	RL ($mg/inch^2$)	Result ($mg/inch^2$)	Permissible Limit ($mg/inch^2$)
			M001	
Distilled Water	Reflux temperature for 7 hours	0.1	0.4	20
	Succeeding 2 hours of extraction	0.1	0.1	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL ($mg/inch^2$)	Result ($mg/inch^2$)	Permissible Limit ($mg/inch^2$)
			M001	
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	*n.d.*	4
Comment	--	--	Pass	--

Test Report No.: 242123010-01 Page 3 of 4

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/inch²)	Result (mg/inch²) M002	Permissible Limit (mg/inch²)
Distilled Water	Reflux temperature for 7 hours	0.1	0.6	20
	Succeeding 2 hours of extraction	0.1	0.1	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/inch²)	Result (mg/inch²) M002	Permissible Limit (mg/inch²)
n-Hexane	Reflux temperature for 7 hours	0.1	0.2	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

Abbreviation: n.d. denotes Not Detected (<RL)
RL denotes Reporting Limit
mg/inch² denotes Milligram per square inch

Sample photo:

242123010-01

M001

M002

- END -

Test Report No. 7191245967-EEC20-WBH
dated 11 Nov 2020

PSB Singapore

Add value.
Inspire trust.

SUBJECT:

Testing of Gloves submitted on 13 Oct 2020 and 16 Oct 2020.

TESTED FOR:

HN Medical Group Co., Ltd.
498/188 Kanchanaphisek Road, Tharang Subdistrict, Bang Khen District, Bangkok, 10220,
THAILAND.

TEST DATE:

14 Oct 2020 to 08 Nov 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Expiry Date	Size	Sample received (pieces)	Manufacturer
1	Disposable Examination Gloves (Powder-Free Blue Nitrile)	-	Blue	HYC04-0720	06-2023	L	400 (200 pcs received on 13 Oct 2020 and 16 Oct 2020 respectively)	HN Medical Group Co., Ltd.

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

METHOD OF TEST:

ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- Clauses 6.1.2 & 7.3 Freedom from Holes (Cross-reference to Test Method D5151)
- Clauses 6.1.3 & 7.4 Physical Dimensions Test
- 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)
- Clauses 6.1.5 & 7.6 Powder-free Residue (Cross-reference to Test Method D6124)

TÜV SÜD PSB

Laboratory:
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Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

RESULTS:

Sample: Disposable Examination Gloves (Powder-Free Blue Nitrile), Lot No. HYC04-0720, Size L

Table 1: Results for Freedom from Holes

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
6.1.2 7.3	Freedom from holes	Shall not leak	10	200	0	Passed

Table 2: Results for Physical Dimensions Test

Clause	Tests	Require-ments (mm)	Results (mm)			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.3 7.4	a) Width	For size L: 110 ± 10	107	107	107	1	13	0	Passed
	b) Length	For size L: ≥ 230	235	239	240				
	c) Finger thickness	≥ 0.05	0.14	0.15	0.16				
	d) Palm thickness	≥ 0.05	0.09	0.10	0.10				

Table 3: Results for Physical Requirements Test – before accelerated aging

Clause	Tests	Require-ments	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	38	41	43	1	13	0	Passed
	Ultimate elongation (%)	≥ 500	538	579	600				

Table 4: Results for Physical Requirements Test – after accelerated aging

Clause	Tests	Require-ments	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	36	41	44	1	13	0	Passed
	Ultimate elongation (%)	≥ 400	552	569	590				

RESULTS (cont'd):

Sample: Disposable Examination Gloves (Powder-Free Blue Nitrile), Lot No. HYC04-0720, Size L

Table 5: Results for Powder-Free Gloves

Clause	Tests	Requirements	Result	Inferred Results
6.1.5 7.6	Powder-free gloves	Powder residue ≤ 2.0 mg	0.28 mg per glove	Passed

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Examination Gloves (Powder-Free Blue Nitrile), Lot No. HYC04-0720, Blue, Size L

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.

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Effective 01 September 2020