



EXAMINATION **GLOVES**



US FDA CERTIFICATE


**Certificate of Registration
2022**

This is to certify that the registration of
HI-CARE THAI GLOVES COMPANY LIMITED
199, MOO 11, T.BANPRU, A, HATYAI,
SONGKHLA, THAILAND - 90250

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is
successfully completed by Liberty Management Group Ltd with the information
provided by Hi-Care Thai Gloves Company Limited

Registration Number 3016855992
Date of Renewal October 5, 2021
Date of Expiration December 31, 2022
US Agent Liberty Management Group Ltd.
Device Listing Numbers See Annex
Certificate Number 3010050221

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**LIBERTY
MANAGEMENT
GROUP LTD.**
75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us


Mamaj Zacharias
President
Liberty Management Group LTD.
Dated: October 5, 2021

ISO 13485:2016 CERTIFICATE

Certificate TH19/11722

The management system of
Hi Care Thai Gloves Co., Ltd.

199 Moo. 11, T. Banru, A. Hatyai, Songkhla 90250, Thailand
has been assessed and certified as meeting the requirements of
ISO 13485:2016
ISO EN 13485:2016

For the following activities:
Manufacture of Non-Sterile Powdered Natural Rubber Latex Examination Gloves
Manufacture of Non-Sterile Powder Free Natural Rubber Latex Examination Gloves
Manufacture of Non-Sterile Nitrile Examination Gloves

This certificate is valid from 08 January 2022 until 08 January 2025 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 08 January 2018.

Authorized by


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Hi-Care Thai Gloves Pvt.Ltd is based in Thailand, operating and manufacturing gloves for medical and examination needs.

We started our journey in the gloves industry in 2005 with a vision to produce superior quality gloves with natural rubber and nitrile.

With 13 years of manufacturing expertise, we believe that every palm needs a trusted layer of protection and we have strived to assure the Hi-Care layer of protection on every glove that we manufacture.

Our operational grip is in Thailand, UAE & India with our own warehouse and marketing divisions

Our Credibility

- > Latest machines with a production capacity of 600 Million gloves per annum
- > Superior quality production
- > Automated stripping, testing and packing facilities
- > Quality complies all national/international standards
- > Latest building designs of EU & FDA standards
- > Competent team for excellent performance

Our Customers are stretched out globally, with the leading ones located in the **USA, UK, Europe, Middle East, Africa & India.**



NITRILE EXAMINATION GLOVES POLYMER COATED (POWDER-FREE)

100% NITRILE
US FDA 510 K
APPROVED



Quality Features

- Biologically compatible
- Softness and shape provides excellent comfort
- Beaded cuff enhances donning and prevent rollback
- High tensile strength and elongation



NITRILE EXAMINATION GLOVES POLYMER COATED (POWDER FREE)

- Manufactured using 100% Synthetic Nitrile (Acrylonitrile Butadiene/NBR)
- Protects against a wide range of chemicals as compared to natural rubber latex of the same thickness.
- Superior strength with better puncture resistance.
- Biologically Compatible.
- Softness and shape provides excellent comfort.
- Beaded cuff enhances donning and prevents rollback.
- High tensile strength and elongation.
- Ambidextrous and straight fingers.
- Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
- Completely free of talc.
- Non Allergic.
- Polymer Coated for easy donning.
- Finger textured for great performance in all conditions.

QUALITY STANDARDS

- Conforms to ASTM D6319 and EN 455 standards.
- Manufactured under QRS (GMP) and ISO 13485:2016 Quality Management System
- An ISO 9001 : 2015 company, CE certified.
- USFDA, 510K Certified.

GLOVE SIZES

- XS, S, M, L, XL
- Marking and labelling as regulatory and customer requirements

GLOVE COLOUR

- White, Blue, Violet Blue, Dark Blue, Bluple
- Or as per customer specification.

PRODUCT SPECIFICATIONS

- Material – Synthetic Nitrile (Acrylonitrile Butadiene or NBR)
- Length – 240 mm +/- 5mm
- Weight – 3.5 to 6.0g +/- 0.3g per piece
- Cuff Style – Beaded
- Surface – Finger Textured
- AQL – 1 - 2.5
- Shelf life - 5 years



NITRILE EXAMINATION GLOVES POLYMER COATED (POWDER FREE) - LONG CUFF

- Manufactured using 100% Synthetic Nitrile (Acrylonitrile Butadiene/NBR)
- Protects against a wide range of chemicals as compared to natural rubber latex of the same thickness.
- Superior strength with better puncture resistance.
- Biologically Compatible.
- Softness and shape provides excellent comfort.
- Beaded cuff enhances donning and prevents rollback.
- High tensile strength and elongation.
- Ambidextrous and straight fingers.
- Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
- Completely free of talc.
- Non Allergic.
- Polymer Coated for easy donning.
- Finger textured for great performance in all conditions.

QUALITY STANDARDS

- Conforms to ASTM D6319 and EN 455 standards.
- Manufactured under QRS (GMP) and ISO 13485:2016 Quality Management System
- An ISO 9001 : 2015 company, CE certified.
- USFDA, 510K Certified.

GLOVE SIZES

- XS, S, M, L, XL
- Marking and labelling as regulatory and customer requirements

GLOVE COLOUR

- White, Blue, Violet Blue, Dark Blue, Bluple
- Or as per customer specification.

PRODUCT SPECIFICATIONS

- Material – Synthetic Nitrile Rubber Latex (Acrylonitrile Butadiene) or NBR
- Length – 300 mm +/- 5 mm
- Weight – 5.0 to 7.0g +/- 0.3g per piece
- Cuff Style – Beaded
- Surface – Finger Textured
- AQL – 1 - 2.5
- Shelf life - 5 years





Hi Care
Thai Gloves Company Ltd.

Hi

- .Quality Latex
- .Protection
- .Packaging
- .Compatibility
- .Strength
- .Elongation



LATEX EXAMINATION GLOVES POWDERED AND POWDER-FREE



Quality Features

- Biologically compatible
- Softness and shape provides excellent comfort
- Beaded cuff enhances donning and prevent rollback
- High tensile strength and elongation
- Ambidextrous and straight fingers

LATEX EXAMINATION GLOVES POLYMER COATED (POWDER FREE)

- Manufactured with high quality and innovative manufacturing technology that makes the glove soft and provides excellent comfort.
- Beaded cuff enhances donning and prevents rollback.
- High tensile strength and elongation.
- Ambidextrous and straight fingers.
- Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
- Extra washing and leaching reduces the possibility of allergic reactions to minimum level.
- Polymer Coated for easy donning.
- Finger textured grip for great performance in all conditions.

QUALITY STANDARDS

- Manufactured under CE standards and ISO 13485:2016 Quality Management System Conforms to ASTM D3578-05, ISO 9001:2015,
- USFDA and EN455 standards.
- Hypoallergenic reducing potential allergic reactions.

GLOVE SIZES

- XS, S, M, L, XL
- Marking and labelling as regulatory and customer requirements

GLOVE COLOUR

- White or Natural Colour.

PRODUCT SPECIFICATIONS

- Material – Natural Rubber Latex
- Length – 240 mm +/- 5mm
- Weight – 5.5g per piece +/- 0.3g
- Cuff Style – Beaded
- Surface – Finger Textured
- AQL – 1 - 2.5
- Shelf life - 5 years



LATEX EXAMINATION GLOVES POWDERED

- Manufactured from natural rubber latex with high quality and innovative manufacturing technology that makes the glove soft and provides excellent comfort.
- Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
- Beaded cuff enhances donning and prevents rollback.
- High tensile strength and elongation.
- Ambidextrous and straight fingers.
- Extra washing and leaching reduces the possibility of allergic reactions to minimum level.
- Powdered with absorbable cornstarch for easy donning and absorption of moisture.
- Smooth grip area for great performance in all conditions.

QUALITY STANDARDS

- Manufactured under CE standards and ISO 13485:2016 Quality Management System
- Conforms to ASTM D3578-05 (2015) and EN 455 standards.
- Hypoallergenic reducing potential allergic reactions.

GLOVE SIZES

- XS, S, M, L, XL
- Marking and labelling as regulatory and customer requirements

GLOVE COLOUR

- White or Natural Colour.

PRODUCT SPECIFICATIONS

- Material – Natural Rubber Latex
- Length – 240 mm +/- 5mm
- Weight – 5g +/- 0.3g per piece
- Cuff Style – Beaded
- Surface – Smooth
- AQL – 1 - 2.5
- Shelf Life - 5 years





OUR EXCLUSIVE RANGE

Latex Examination Gloves Powdered

Latex Examination Gloves Powder-Free

Nitrile Examination Gloves Powder-Free

Nitrile Examination Gloves, Long Cuff.



QUALITY ASSURANCE

Product meets all stated and implied needs.

Manufactured under hygiene and environment control.

Superior barrier protection.

No allergy risks.

Scientifically tested gloves.

Standardized and Customized Packing.

Well equipped microbiology lab.

State-of-the-art manufacturing, inspection, and packing facilities.





EN455
Parts 1-4



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