



EXAMINATION **GLOVES**

US FDA CERTIFICATE

ISO 13485:2016 CERTIFICATE



Certificate of Registration 2025

This is to certify that the registration of
HI-CARE THAI GLOVES CO LTD
89/1, MOO 4, TAMBON CHALUNG, A. HATYAI,
SONGKHLA, THAILAND - 90110

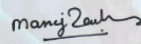
with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by HI-CARE THAI GLOVES CO LTD

Registration Number	3020764656
Date of Renewal	December 8, 2024
Date of Expiration	December 31, 2025
U.S Agent	Liberty Management Group Ltd.
Device Listing Numbers	See Annex
Certificate Number	3012080224

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

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. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.

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


Manoj Zacharias
President
Liberty Management Group LTD.
Dated: December 8, 2024

Certificate TH19/11722

The management system of

Hi - Care Thai Gloves Co., Ltd.

89/1 Moo 4, Tambon Chalung, Amphoe Hatyai, Songkhla Province 90110, Thailand
has been assessed and certified as meeting the requirements of
ISO 13485:2016
EN ISO 13485:2016

For the following activities
Manufacture of Non-sterile Powdered Rubber Latex Examination Gloves.
Manufacture of Non-sterile Powder Free Rubber Latex Examination Gloves.
Manufacture of Non-sterile Nitrile Powder Free Examination Gloves.

This certificate is valid from 08 January 2025 until 07 January 2028 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 08 January 2019

L. Moran

Authorised by
Liz Moran
Business Manager

SGS United Kingdom Ltd
Rosemore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-0606 - www.sgs.com



This document is an authentic electronic certificate for Client business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions (SGS). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



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 Milion 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 preformance

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

- .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.

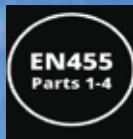
Scientifically tested gloves.

Standardized and Customized Packing.

Well equipped microbiology lab.

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





FACTORY:

89/1 Moo. 4, T.Chalung, A.Hatyai
Songkhla 90110, Thailand.

Tel: +66 74 291043, 291044

Mobile : +66 9222 58472

E-mail: sales@hicarethai.com



Handling you with care

82/2, Moo 9, Rattaphum, Khuan Neing,
Songkhla, 90220, Thailand

Tel: +66 74 302100

E-mail : dptl.factory@dplgroup.com