



**EXAMINATION GLOVES**



**Hi Care**  
Thai Gloves Company Ltd.



## Certificate of Compliance

# CE

We hereby declare that the technical file of product complies with the requirements of EC directive 93/42/EEC Medical Device Directive (MDD).

Certificate No.: CE-3399

**Manufacturer**

Name : HI CARE THAI GLOVES CO. LTD.  
Address : 199 Moo. 11 T. Banpru A. Hatyai Songkhla 90250, Thailand

**Products** : Latex Examination Glove-Powdered, Latex Examination Glove- Powder Free, Nitrile Examination Glove- Powdered, Nitrile Examination Glove Powder Free, House Hold Glove Powdered, House Hold Glove Powder Free, Latex Surgical Glove Non Sterile Powdered, Latex Surgical Glove Non Sterile Powder Free

**Complies with the requirements applicable to it**  
The Certification body has performed an audit of the above product quality system, covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive EC Directive 93/42/EEC Medical Device Directive (MDD).

**This certificate is issued under the following conditions:**

- It applies only to the quality system maintained by the manufacturer of above referenced models and it does not relate to the design or type examination procedure, if requested.
- The certificate remains valid until the manufacturing conditions or the quality system are changed.
- The certificate validity is conditioned by positive results of surveillance audits.
- After holding the relevant EC legislation, the manufacturer shall refer to each device of the referenced models.
- The CE mark or other marks can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at [www.ukcertifications.co.uk/verify](http://www.ukcertifications.co.uk/verify)

|   |                             |
|---|-----------------------------|
| Date of Certification   | 09 <sup>th</sup> April 2018 |
| 1 <sup>st</sup> Surveillance Audit Due  | 08 <sup>th</sup> April 2019 |
| 2 <sup>nd</sup> Surveillance Audit Due  | 08 <sup>th</sup> April 2020 |
| Certificate Expiry (subject to the company maintaining its system in the required standard) | 08 <sup>th</sup> April 2021 |

*David ..*  
Authorised Signatory



This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.  
15-19 Market Street, Christ Church, London, W1D 3HQ, United Kingdom  
Website: [www.ukcertifications.co.uk](http://www.ukcertifications.co.uk), email: [info@ukcertifications.co.uk](mailto:info@ukcertifications.co.uk)  
Company No. 10171947

## CERTIFICATE



### HI-CARE THAI GLOVES CO. LTD.

ADDRESS: 199 MOO.11 T. BANPRU A. HATYAI SONGKHLA 90250, THAILAND

### QACS INTERNATIONAL

*Certify that the quality management system of the above organisation has been audited and found to be in accordance with the requirements of standard detailed below.*

## ISO 9001:2015

MANUFACTURING & MARKETING OF STERILE LATEX SURGICAL GLOVES (POWDERED & POWDER FREE), NON STERILE LATEX SURGICAL GLOVES (POWDERED & POWDER FREE), STERILE LATEX EXAMINATION GLOVES (POWDERED & POWDER FREE), LATEX STERILE LATEX EXAMINATION GLOVES (POWDERED & POWDER FREE), STERILE NITRILE EXAMINATION GLOVES (POWDERED & POWDER FREE) & NON STERILE NITRILE EXAMINATION GLOVES (POWDERED & POWDER FREE) & HOUSE HOLD GLOVES (POWDERED & POWDER FREE)

Certificate No:- QAIS-Q-HC-02.18.025

*This certification was conducted in accordance with the qacs international LCC auditing and Certification procedures and it is remain valid subject to annual surveillance audits.*

|   |  |
|---|--|
| Certificate Issue Date: 09 April 2018       | 1 <sup>st</sup> Surveillance Date: 08 April 2019 |
| Date of Initial Registration: 08 April 2018 | 2 <sup>nd</sup> Surveillance Date: 08 April 2020 |
| Certificate Validity:- 3 Years              | Re-certification Date:- 08 April 2021            |

*Note: Certificate shall be valid after surveillance, only if continuation letter by QACS is present.*

To Check the certificate validity please  
Refer Web:- [www.qacs.com/uk](http://www.qacs.com/uk)




*Bill*  
Authorised Signatory



**H**i-Care Thai Gloves Pvt.Ltd is based in Thailand, operating and manufacturing gloves for medical, examination, surgical & household needs.

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

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.

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

#### **Our Credibility**

- > Latest machines with a production capacity of 450 Million pairs of 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 suppliers are stretched out globally, with the leading ones located in the US, Gulf countries, South Africa, Egypt, & India.

**NITRILE EXAMINATION GLOVES POLYMER COATED (POWDER-FREE)**



**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 Rubber Latex (Acrylonitrile Butadiene)
- 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.
- Fully textured grip 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 1817 company, CE certified.
- ISO 1817:2011, RUBBER VULCANISED DETERMINATION OF THE EFFECT OF LIQUIDS.

## 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)
- Length – 240 mm +/- 5mm
- Weight – 3.5 to 6.0g +/- 0.3g per piece
- Cuff Style – Beaded
- Surface – Palm Textured
- AQL – 1 - 2.5



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

- Manufactured using 100% Synthetic Nitrile Rubber Latex (Acrylonitrile Butadiene)
- 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.
- Fully textured grip for great performance in all conditions.

### QUALITY STANDARDS

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### GLOVE SIZES

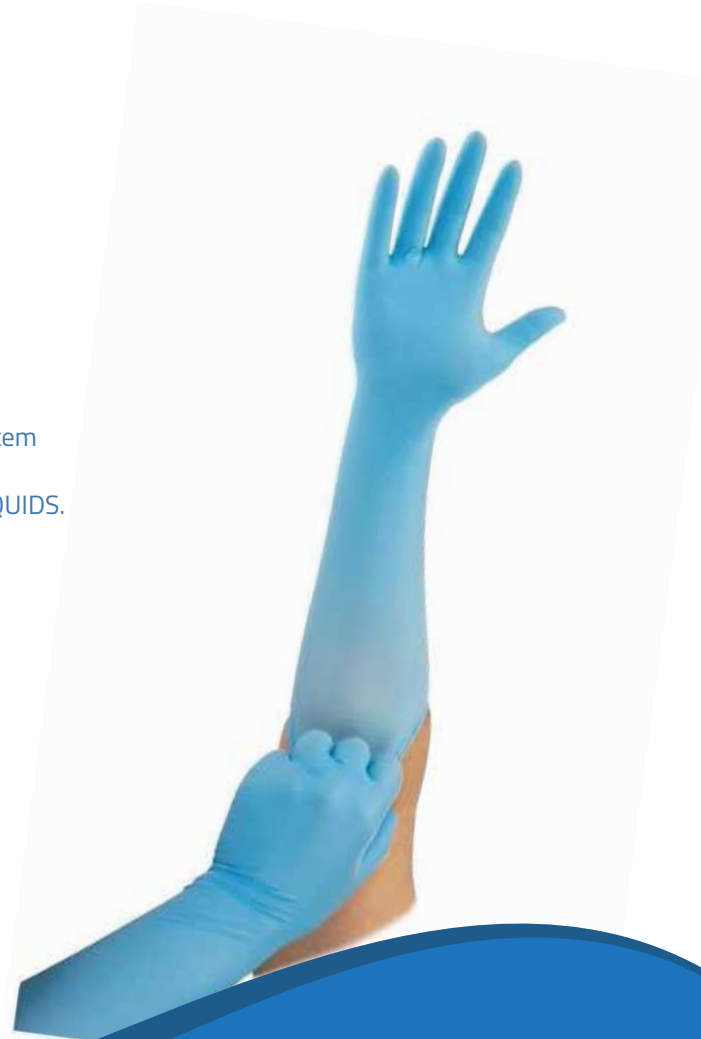
- XS, S, M, L, XL  
Marking and labelling as regulatory and customer requirements

### GLOVE COLOUR

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

### PRODUCT SPECIFICATIONS

- Material – Synthetic Nitrile Rubber Latex (Acrylonitrile Butadiene)
- Length – 290 mm +/- 5 mm
- Weight – 5.0 to 7.0g +/- 0.3g per piece
- Cuff Style – Beaded
- Surface – Palm Textured
- AQL – 1 - 2.5





**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.
- Fully 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(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, Blue.
- Or as per customer specification.

## PRODUCT SPECIFICATIONS

- Material – Natural Rubber Latex (Type-1)
- Length – 240 mm +/- 5mm
- Weight – 5.5g per piece +/- 0.3g
- Cuff Style – Beaded
- Surface – Palm Textured
- AQL – 1 - 2.5



## 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.
- Textured palm and 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, Blue, Green
- Or as per customer specification.

## PRODUCT SPECIFICATIONS

- Material – Natural Rubber Latex (Type-1)
- Length – 240 mm +/- 5mm
- Weight – 5g +/- 0.3g per piece
- Cuff Style – Beaded
- Surface – Palm Textured
- AQL – 1 - 2.5
- Shelf Life -





## OUR EXCLUSIVE RANGE

Sterile Powdered Latex Surgical Gloves

Sterile Powder-Free Latex Surgical Gloves

Latex Examination Gloves Powdered

Latex Examination Gloves Powder-Free

Nitrile Examination Gloves Powder-Free

Household Gloves Powder-free



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## 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

199 Moo. 11, T.Banpru, A.Hatyai,  
Songkhla 90250, Thailand.

Tel: +66 74 291043, 291044

E-mail: [sales@hicarethai.com](mailto:sales@hicarethai.com)



### Our Branches:

**Bangkok:** 541, Bangweak 61,  
Soi Chaisangun, Bangweak Road,  
Bhasicharoen, Bangkok-10160,  
Mob: +66945954004 (Mr. Aby-Director Marketing, Bangkok)  
& +66922258473 (Mr. Alen-Marketing Manager, Bangkok)  
Email: [hicarethaimarketing@gmail.com](mailto:hicarethaimarketing@gmail.com)

**UAE:** Alreayah Alaliah Plastic TR.LLC  
P.O Box: 61856, Ind.Area-11, Street 31 Shed No.2, Sharjah  
Mob+971547923511 (Mr. Rajesh-Director Marketing, UAE)  
& +971547923512 (Mr. Martin-Marketing Manager, UAE)  
Email: [highcareuae@gmail.com](mailto:highcareuae@gmail.com)

**India:** Wecare Importers & Marketing  
IX/575b, Arumanoor P.O, Kottayam- 686568  
Mob +919539078883 (Mr. Roy-Director Marketing, India)  
E-mail: [wecareimporters@gmail.com](mailto:wecareimporters@gmail.com)

