

COVID-19 Vglove Non-sterile Powder-free Latex / Nitrile gloves 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Australia | Canada | China | Japan | The Netherlands | United States

EMERGO EUROPE

26 May 2009

Mr. Terence Lim
Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Binh Duong
Vietnam

Dear Terence:

I am writing to inform you that today, we have notified by registered mail the Dutch Competent Authority.

With this notification, Khai Hoan Joint Stock Company has met the requirements of Article 14 of the Medical Devices Directive, 93/42/EEC for the following devices:

- Powder Examination Gloves
- Powder-Free Examination Gloves

As of today and without any further notice from the respective Competent Authorities, Khai Hoan Joint Stock Company can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,



Rene van de Zande
President & CEO

EmergoEurope.com

Emergo Europe Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570 Fax: +31.70.346.7299



Australia | Canada | China | Japan | The Netherlands | United States

EMERGO EUROPE

CE Registration Certificate

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

**Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Binh Duong Province
Vietnam**

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received Medical Device Registrations on the following date:

**26 May 2009
See attached product listing**

Emergo Europe Registration Number: NL/CA01/601529

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the Medical Devices fulfill the applicable requirements of Directive 93/42/EEC.

June 2009



Rene van de Zande
President & CEO
Emergo Europe

EmergoEurope.com

Emergo Europe Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570 Fax: +31.70.346.7299



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bsi.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

VRG KHAI HOAN JOINT STOCK COMPANY
Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number: **MD 548620**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

**The manufacture and distribution of:
Non-sterile, powder, powder free natural latex examination gloves
Non-sterile, powder free nitrile examination gloves.**

For and on behalf of BSI:

Stewart Brain
Stewart Brain, Head of Compliance & Risk – Medical

Original Registration Date: **18/05/2009**

Effective Date:

Latest Revision Date: **02/05/2018**

Expiry Date:



MD 548620

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/Certificates or by telephone. Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements to the organization. This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK15 8PP, Tel: +44 (0)1908 9000
BSI Assurance UK Limited, registered in England under number 7805331 at 139 Chiswick High Road, London W4 4AL, UK.
A member of the BSI Group of Companies.



ISO 22000:2005



13485:2016

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Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000:2005

This is to certify that:

VRG KHAI HOAN JOINT STOCK COMPANY
Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number:

FSMS 552546

FSMS 552546

and operates a Food Safety Management System which complies with the requirements of ISO 22000:2005 for the following scope:

**The manufacture and distribution of:
Non-sterile, powder, powder free natural latex examination gloves;
Non-sterile, powder free nitrile examination gloves.**

Category: **I**

For and on behalf of BSI:

Chris Cheung
Chris Cheung, Head of Compliance & Risk – Asia Pacific

Original Registration Date: **09/10/2009**

Effective Date: **09/10/2018**

Latest Revision Date: **14/07/2018**

Expiry Date: **18/06/2021**



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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

VRG KHAI HOAN JOINT STOCK COMPANY
 Cau Sat Hamlet,
 Lai Hung Commune,
 Bau Bang District,
 Binh Duong Province,
 Vietnam

Holds Certificate Number:

FM 548618 FM 548618

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**The manufacture and distribution of:
 Non-sterile, powder, powder free natural latex examination gloves;
 Non-sterile, powder free nitrile examination gloves.**



For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk – Asia Pacific

Original Registration Date: **01/06/2009**

Effective Date: **01/06/2018**

Latest Revision Date: **30/05/2018**

Expiry Date: **31/05/2021**

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COVID-19

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코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑



Issued to:

VRG Khai Hoan JSC
Cau Sat Hamlet
Lai Hung Commune
Bau Bang District
Binh Duong Province
Vietnam

Notified Body: 2777

SATRA customer number: P1434

EU Type-Examination Certificate

Certificate number: 2777/11582-01/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:

PFNBR

Description:

Non-sterile powder free nitrile examination gloves

Sizes:

XS/6, S/7, M/8, L/9, XL/10

Classification:

EN ISO 374-1: 2016 / Type B

40% Sodium hydroxide (K)

30% Hydrogen peroxide (P)

37% Formaldehyde (T)

EN ISO 374-5: 2016

Protection against Bacteria and fungi

Protection against viruses

Level

6

4

6

Pass

Pass

EN ISO 374-4:2013 % Degradation

-13.2

5.3

4.6

Standards/Technical specifications applied:

EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: SPC0225034/1420/2, SPC0225034/1420/SMcD/B, SPC0244727/1615, CHM0248775/1632/SMcD, CHM0272778/1827/LH, CHM0276386/1840/JH, SPC0244727/1615, SPC0273658/1830, CHM0273594/1830/LH/A, CHM0273594/1830/LH/B, CHM0273594/1830/LH/C
TUV: 7191169844-CHM17-01-RC

Signed on behalf of SATRA:

Tara Saunders

Austin Simmons

Date first issued: 23/11/2018

Date of issue: 23/11/2018

Expiry date: 23/11/2023

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Customer details: VRG Khai Hoan Joint Stock Company
Cau Sat Hamlet
Lai Hung Commune
Ben Cat District
Binh Duong
Vietnam

SATRA reference: SPC0225034 /1420/2

Your reference:

Date of report: 5 July 2014

For the attention of: Tra Trang

Samples received: 16 May 2014

TECHNICAL REPORT

Subject: Testing of gloves described as "PFNBR" in accordance with EN 388: 2003, EN 420: 2003 + A1: 2009 & EN 374-2: 2003

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked † fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides for a confidence level of approximately 95%

Report signed by: D Harrison
Position: PPE Technologist
Department: Safety Products Centre

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TECHNICAL REPORT



Work Requested

Samples of gloves, see Table 1 were received by SATRA, for testing in accordance with EN 388:2003, EN 420:2003 + A1:2009 and EN 374-2:2003.

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove Size: 10 Weight: 4.8g
PFNBR	7 - 10	White, Blue and Purple	



Conclusion

Standard	Clause / Property	Result
EN 420:2003 + A1:2009	5.1 Length and fit	See Note A
	5.2 Dexterity	Level 5
EN 388:2003	6.1 Abrasion resistance	Level 0
	6.2 Blade cut resistance	Level 0
	6.3 Tear resistance	Level 0
	6.4 Puncture resistance	Level 0
EN 374-2:2003	4.1 Air Leak Test	Pass
	4.2 Water Leak Test	Pass

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Test Report No. 7191212955-EEC19/03-WBH_CR2
(re-issue dated: 21 Jun 2019)
dated 14 Jun 2019



PSB Singapore

Add value.
Inspire trust.

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:

Glove testing for freedom from hole.

TESTED FOR:

VRG Khai Hoan Join Stock Company
Cau Sat Hamlet
Lai Hung Commune
Bau Bang Dist
Binh Duong Province
Vietnam

SAMPLE SUBMISSION DATE:

07 Jun 2019

TEST DATE:

11 Jun 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Lot No.	Sample received	Manufacturer
1	Nitrile Gloves	-	6 boxes (100 pieces per box)	VRG Khai Hoan Join Stock Company

Lot size as specified by client: 150,001 to 500,000 pieces

Amendments:

The following amendments were made on 19 Jun 2019 and 21 Jun 2019:
The "Product Description" and "Manufacturer" under "DESCRIPTION OF SAMPLES" were amended as requested by client.

The "Client" under "TESTED FOR" was amended as requested by client.



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 dated 14 Jun 2019



PSB Singapore

METHOD OF TEST:

As requested by client, the test was conducted as follows:

EN 455-1:2000 Medical gloves for single use
 Part 1: Requirements and testing for freedom from hole

RESULTS:


Sample: Nitrile Gloves

Table: Results for EN 455-1:2000

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	10	315	1	Passed

REMARKS:

- The manufacturing batch code was not provided by the client.


 Yeo Poh Kwang
 Associate Engineer


 Wong Bee Hui
 Product Manager
 Medical Health Services (NAM)

