

## PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

### Vinylové rukavice VINYL CLASSIC

#### ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	polyvinylchloridová pastová pryskyřice
Barva:	bílá - průhledná
Provedení:	pravolevé, hladké, manžeta
Pudr:	uvnitř rukavice vstřebatelný kukuřičný škrob USPXX1
Skladování:	rukavice neztrácejí své vlastnosti při skladování v suchu při teplotě od 10 do 30 °C
Životnost:	5 let od data výroby při dodržení podmínek skladování
Balení:	100 ks v krabičce, 10 krabiček v kartonu

#### ČÁST II: SPECIFIKACE PRODUKTU

Délka (mm):	min. 230
Šířka (mm):	XS – 75 ± 5 S – 85 ± 5 M – 95 ± 5 L – 105 ± 5 XL – 115 ± 5
Tloušťka (mm):	prsty: 0.05–0.06 dlaň: 0.05–0.07
Prodloužení do přetržení (%):	min. 300
Pevnost v tahu (MPa):	min. 11
AQL:	1.5



### ČÁST III: NORMY A NAŘÍZENÍ

Tímto potvrzujeme, že výše uvedený výrobek je v souladu s:

Obecné: PPER (EU) 2016/425 Cat. I  
EN 420

Potravinářství: EC 1935/2004  
EC 2023/2006  
EU 10/2011 \* Vyhovuje pro všechny simulanty kromě 3% kyseliny octové. Tento produkt je vhodný pro manipulaci s potravinami, kromě kyselých potravin (testováno 2 hodiny při 40 ° C)

### ČÁST IV: POLOŽKY

Pol. č.	Velikost	Hmotnost (g)	Rozměry (mm)	Kvalita (g)	EAN
100000	S	483	220×125×65	4.3 ± 0.2	8594177200018
100001	M	531	220×125×65	4.8 ± 0.2	8594177200025
100002	L	576	220×125×65	5.3 ± 0.2	8594177200032
100009	XL	635	220×125×65	5.8 ± 0.2	8594177200049

### ČÁST V: NÁHLED PRODUKTU





## ČÁST VI: PŮVOD PRODUKTU

Výrobce:

GREATGLOVE (Xinghua) Co., Ltd, Sotuh of Wei Wu Road, 225700 Xinghua, China  
INTCO Medical Technology Co., Ltd, No. 29 Zhangliu Road, Zibo, Shandong, China

Distributor:

Espeon s.r.o., U větrolamu 1212/53, 184 00 Praha 8, [info@espeon.cz](mailto:info@espeon.cz), [www.espeon.cz](http://www.espeon.cz)



## **GREAT GLOVE (XINGHUA) CO. LTD.**

**The World's Largest Manufacturer of Gloves**

**TOP QUALITY, TOP EFFICIENCY, GOOD HEALTH, SAFETY FIRST & BE HONEST**

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

: South of Wei Wu Road, Economic Developing District, Xinghua 225700 Jiangsu Province, China.

☎ +86-523-8326 8976 📠 +86-523-8326 8676 ✉ great@topglove.com.my 🌐 www.topglove.com

**FACTORY 15**

**BUSINESS DIRECTION**

: To Produce Consistently High Quality Gloves At Efficient Low Cost.

**FACILITIES**

: 40 Factories (Malaysia, Thailand & China), 648 Production Lines, 60.5 Billion Gloves Per Annum, 18,000 Employees.

**MARKET**

: Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

### **DECLARATION OF CONFORMITY**

Manufacturer's Name : GREAT GLOVE (XINGHUA) CO. LTD.

Manufacturer's Address : South of Wei Wu Road, Economic Developing District,  
Xinghua 225700, Jiangsu Province, China  
TEL : 8652383268976, FAX : 8652383268676

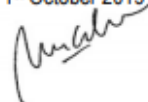
Name of Devices & Types as below :

No	Name of Devices	Types
1	Vinyl Examination Gloves	Powdered
2	Vinyl Examination Gloves	Polymer Powder Free

Classification : **PPE Category I** (For Minimal Risk Only)

I, the undersigned, hereby declare that the disposable device(s) specified above conform to the Essential requirements listed in Personal Protective Equipment (PPE) Regulation EU 2016/425 as self-declaration providing protection against for Minimum Risks concerned the effects of which, when they are gradual, can be safely identified by the user.

Date : 1<sup>st</sup> October 2019.



NOOR AKILAH SAIDIN - DEPUTY GM, RA.



**TOP GLOVE SDN. BHD.** (Company No. 220483-T)  
**TOP QUALITY, TOP EFFICIENCY,  
 GOOD HEALTH, SAFETY FIRST & BE HONEST**

\* A member of Top Glove Corporation Bhd, Public Listed Company on Bursa Malaysia.  
 Latex Examination, Nitrile, Surgical, Vinyl & Household Gloves Manufacturer and Exporter  
 The World's Largest Rubber Glove Manufacturer

Corporate Office : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D. E., Malaysia.  
 & Factory 9 Tel: 603-3392 1992 / 1905 Fax: 603-3392 8410 / 1291  
 E-mail : sales@topglove.com.my Website : www.topglove.com.my



<b>BUSINESS DIRECTION</b>	: To Produce Consistently High Quality Gloves At Efficient Low Cost.
<b>FACILITIES</b>	: 25 Factories (Malaysia, Thailand & China), 487 Production Lines, 45 Billion Gloves Per Annum, 11,000 Employees
<b>MARKET</b>	: Exports to more than 185 countries worldwide with Marketing offices in the USA and Germany.

Date: 8<sup>th</sup> May 2014

To: Whom It May Concern

**Subject: LETTER OF DECLARATION**

This is to certify that our production of Vinyl Examination Powdered and Powder Free Gloves comply with EU Food regulation 1935/2004 and 2023/2006 and tested according to requirements of the Plastic Materials and Articles in contact with food commission follow the new Regulation (EU) No. 10/2011 of 14 January, 2011.

Verified by

.....  
 Pn Noor Akilah Saidin  
 QA Deputy General Manager

RA/LOD/034/04/14-1



GERMANY



EUROPE



U.S.A.



AUSTRALIA



CANADA



MALAYSIA

**"To Prevent & Against Corruption" and "Be Honest, No Cheating"**



**Test Report**

**No: SHFDO120100213FD**

**Date: Jan 18 2012**

Client name: Great Glove (XingHua) Co.,Ltd.  
Client address: South of Wei Wu Road, West of XiHuan Road, Developing District, XingHua City,  
JiangSu Province. China

**The following sample(s) was/were submitted by/ on behalf of the client as (except SGS reference No. & SGS job No. & Date of receipt & Testing period):**

Sample name: Vinyl Examination Powdered Gloves  
Batch No./Date: 120105051  
Manufacturer: Great Glove(Xing Hua) Co.,Ltd.  
SGS reference No.: SHAFD1200259001  
SGS job No.: SHFDO120100213FD  
Date of receipt: Jan 09 2012  
Testing period: Jan 09 2012 ~ Jan 17 2012

**TEST(S) REQUESTED:**

Selected test(s) as requested by applicant:

For compliance with Commission Regulation (EU) No 10/2011 of 14 January 2011 and Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on plastic materials and articles intended to come into contact with food.

- 1) To determine the Overall Migration.
- 2) To determine the Specific Migration of Heavy Metal.
- 3) To determine the VCM-vinyl chloride monomer with reference to Commission Regulation (EU) No 10/2011 of 14 January 2011.

**TEST METHOD(S):**

Please refer to next page

**TEST RESULT(S):**

Please refer to next page

**CONCLUSION:**

When tested as specified, the tested parameters comply with the requirements stated in Commission Regulation (EU) No 10/2011 of 14 January 2011 and Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on plastic materials and articles intended to come into contact with food.

Signed for and on behalf of SGS



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RAND: 5602013

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SGS-CTI Technical Services (Shanghai) Co., Ltd. 3<sup>rd</sup> Building No. 689, Yishan Road, Shanghai, China 200233 t (86-21)61402998\*2785 f (86-21)64500454 www.cn.sgs.com  
Testing Center (Shanghai) Laboratory 中国·上海·宜山路689号3号楼 邮编: 200233 t (86-21)61402998\*2785 f (86-21)64500454 e sgs.china@sgs.com

SHFD

Member of the SGS Group (SGS SA)



**Test Report**

**No: SHFDO11226875FDS1**

**Date: Jan 06 2012**

**TEST METHOD(S):**

- 1) With reference to 82/711/EEC with its amendments and 2002/72/EC with its amendments for selection of condition and EN1186-1:2002 for selection of test method  
EN1186-3:2002 aqueous food simulants by total immersion method;  
EN 1186-14:2002 substitute test
- 2) With reference to 82/711/EEC with its amendments and 2002/72/EC with its amendments for selection of condition and EN13130-1:2004 for selection of test method; analysis was performed by ICP-OES.
- 3) In-house method (SHTC-CHEM-SOP-171-T), analysis was performed by HS-GC-MS.

**TEST RESULT(S):**

- 1) Overall migration

Simulant Used	Time	Temperature	Max. Permissible Limit (mg/dm <sup>2</sup> )	Result of Overall Migration (mg/dm <sup>2</sup> )
3% Acetic Acid (W/V)	2.0hr	70°C	10	< 3.0
10% Ethanol (V/V) Aqueous Solution	2.0hr	70°C	10	< 3.0
50% Ethanol (V/V) Aqueous Solution	2.0hr	70°C	10	6.9
95% Ethanol (V/V) Aqueous Solution (Rectified Oliver Oil Substitute)	2.0hr	60°C	10	6.9
Isooctane (Rectified Oliver Oil Substitute)	0.5hr	40°C	10	< 3.0
20% Ethanol (V/V) Aqueous Solution	2.0hr	70°C	10	< 3.0

Notes :

- (1) mg/dm<sup>2</sup> = milligram per square decimeter
- (2) °C = degree Celsius
- (3) <= less than
- (4) Analytical tolerance of aqueous simulants is 1 mg/dm<sup>2</sup>
- (5) Analytical tolerance of fatty food simulants is 3 mg/dm<sup>2</sup>
- (6) Test condition & simulant were specified by client.

- 2) Specific Migration of Heavy Metal

Simulant Used: 3% Acetic Acid (W/V) Aqueous Solution

Test Condition: 70°C 2.0hr

Test Item(s)	Limit	Test Result(s)	Method Detection Limit(s)
Barium	1	Not detected	0.25
Cobalt mg/kg	0.05	Not detected	0.05
Copper mg/kg	5	Not detected	0.25
Iron mg/kg	48	Not detected	0.25
Lithium mg/kg	0.6	Not detected	0.5
Manganese mg/kg	0.6	Not detected	0.25
Zinc mg/kg	25	Not detected	0.5

Note: Test condition & simulant were specified by client.

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RAND: 5610117

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SGS-CSI Technical Services (Shanghai) Co., Ltd. 3<sup>rd</sup> Building, No. 889, Yishan Road, Shanghai, China 200233 t (86-21)61402666/2785 f (86-21)54500454  
中国·上海·宜山路889号3号楼 邮编: 200233 t (86-21)61402666/2785 f (86-21)54500454

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e.sgs.china@sgs.com





**Test Report**

**No: SHFDO111226875FDS1**

**Date: Jan 06 2012**

**3) Vinyl Chloride Monomer (VCM)**

Test Item(s)	Limit	Test Result(s)	Method Detection Limit(s)
VCM(Vinyl Chloride Monomer)	1	Not detected	0.5

**SAMPLE DESCRIPTION:** White stick in bag



\*\*\* End of Report\*\*\*



## EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

*Name:* Shandong Intco Medical Products Co., Ltd.  
*Address:* Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

*Name:* Lotus NL B.V.  
*Address:* Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Declares that the MDR described hereafter

*Product name and model:*

**Disposable Vinyl Exam Gloves / SYNGUARD® Vinyl Exam Gloves**

**EMDN code: T01020201**

**Model:** XS /S /M /L /XL/XXL

**Product Code:** VGV/B/H/PEM, SVV/B/H/PE (Please refer to the attachment for more details).

**Basic UDI-DI:** 697024575Vinyl85

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

**Shandong Intco Medical Products Co., Ltd.**

**SRN:** CN-MF-000002100

Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016

EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-5:2009.

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them,

The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII

Chapter III of the Regulation EU 2017/745 MDR. It bears the mark



We agree to develop, implement and maintain a documented post-production monitoring process.

Shandong 2021-07-22

*Place, date*

Rick Cheng Quality Manager

*Legally binding signature function*





 英科医疗	山东英科医疗制品有限公司 Shandong Intco Medical Products Co., Ltd.	文件编号 Doc No.	INTCO-PVC-FDOC
		版本 Ver.	A0

## Declaration of Conformity for Food Contact

Manufacturer Name: Shandong Intco Medical Products Co.,Ltd.

Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

Declares that the disposable Vinyl gloves , made of Polyvinyl Chloride as main material, that meet relevant requirements laid down in Regulation (EU) No 10/2011 and Regulation (EC) No 1935/2004 and Regulation (EC) No 2023/2006;

The Vinyl gloves may be used safely for the preparation and handling of foodstuff and may stand in direct contact for all kind of food stuff except fatty foods with a maximum temperature of 40 °C for 30 min

This Declaration of conformity is valid for three years: 6 / Jan / 2021 to 5 / Jan / 2024. If there is a change in the declaration information, this declaration is invalid.

The above mentioned declaration of conformity is exclusively under the responsibility of

**Company: Shandong Intco Medical Products Co., Ltd.**

**Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China.**

Shandong 2021-01-06

*Place , date*  
*Function*

Rick Cheng Quality Manager

*Legally binding signature,*