



DISPOSABLE SYNTHETIC NITRILE GLOVES CE & FDA APPROVED QUALITY

E3E Earth Emergency Exchange

Götgatan 22A 11846 Stockholm, SWEDEN

www.E3E.org





- · Brand new product
- DOP-free
- No latex proteins, low allergy potential
- · Comfortable conforming latex-like fit
- · Effective barrier and extra strength
- Enhanced tactile sensitivity
- Popular Color in Blue or White
- Economical protection
- AQL 1.5

Quality Standard

- Complies with EN 455 and EN 374
- Complies with ASTM D5250 (USA Related Product)

Technical Information	
REF:	E3E-S001
Product type:	Powder-free, unsterile
Main material:	Synthetic Nitrile: Compound of Vinyl-based Hybrid
Colour:	Blue, white
Model:	Ambidextrous, with rolled rim
Storage:	Protect from heat, humidity, strong light and ozone
Size/overall length as per EN 455-2:	XS, S, M, L and XL 240mm (≥230mm for USA)
Impermeability as per EN 455-1:	AQL1.5
Shelf Liferd:	Min. 5 years



Features

- The donning feeling is better than vinyl gloves.
- The wearing time is longer than nitrile gloves.
- · Better cost-performance, effectively reduce customers'
- PU coating, with no protein in it, allergy risk is reduced effectively.
- · Better protection, good resistance of acid, alkali and oil.
- · Popular color in blue, black, purple, pink, yellow and white.



























Quality standards

- Complies with EN 455 and EN 374
- Complies with ASTM D5250 (USA Related Product)

Туре	Material .	Color	Model	Storage	Size/overall length as per EN455-2		Durability,in original packaging if stored as per din 7716,ISO 2230
Powder-free non-sterile	Compound of vinyl-based hybrid	Blue, black, purple, pink, yellow, white	Ambidextrous with rolled rim	Protect from heat, humidity, strong light and ozone	S M L XL 240 mm (≥230mm for USA)	AQL1.5	Min. 5 years









Document Number: E3E-CE-DC-GLV-S001, S002, & S003

EC DECLARATION OF CONFORMITY

We,

E3E Earth Emergency Exchange AB

Sveavägen 35, 111 34 Stockholm, SWEDEN

under the responsibility as an importer, declare that the following product described hearafter:

POWDER FREE SYNTHECTIC NITRILE EXAMINATION GLOVES / **DISPOSIBLE SYNTHETIC NITRILE GLOVES** BLUE COLORED, NON-STERILE, MIXED SYNTHETIC MATERIALS

manufactured by our assigned facilities.

is in conformity with the provisions of

- 1) Medical Device Regulations (EU) 2017/745, under Class I Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards, EN 455 and meets requirement of Council Directive 93/42/EEC.
- 2) Personal Protective Equipment Regulation (EU) 2016/425, under Category III risk per set out in Annex I, complying with European standards EN 374. It is identical to the PPE which is subject to the EU Type Examination (Module B) under certificate number 2777/10015-03/E00-00 issued by Notified Body:

SATRA Technology Europe Limited (2777)

Bracetwon Business Park, Colnee, Dublin 15, D15YN2P, Ireland

And it is subject to the annual conformity assessment procedure which is based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified Body:

SATRA Technology Europe Limited (2777)

Bracetwon Business Park, Colnee, Dublin 15, D15YN2P, Ireland

The above mentioned product demonstrates fulfillment to the essential health and safety requirements set out in Annex II of PPE Regulation (EU) 2016/425.

The product is imported by E3E Earth Emergency Exchange AB and manufactured by Sandong Intco Medical Products Co., Ltd., Hongray Group, and Guangdong Shenpu Technology Co., Ltd and our assigned facilities. And the Medical Devices has been assigned to Class I according to Annex VIII of the Regulation EU 2017/745 and the Personal Protective Equipment Regulation has been assigned to Class III according Annex I of PPE Regulation (EU) 2016/425. This Declaration of Conformity is valid in connection with the release document for the respective batch of the produced devices.

Signature:

Name: VANESSA FOLKESSON Position: MANAGING DIRECTOR Place: Stockholm, SWEDEN Date: 20th September 2020

Signed on behalf of E3E Earth Emergency Exchange AB



Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shijiazhuang Hongray Group Co., Ltd. South Tongda Rd., East Dist. Jinzhou 052260 Hebei P.R. China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Patient Examination Gloves (see attachment for sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2020-04-16

Certificate Registration No.:

SX 60148697 0001

An audit was performed. Report No.: 16801058 009

This Certificate is valid until:

2020-10-25

Certification Body



Date 2020-04-16



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.; +49 221 806-1371 Fax; +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety



Doc. 1/3, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to

Certificate

Registration No.: SX 60148697 0001 Report No.: 16801058 009

Organization:

Shijiazhuang Hongray

Group Co., Ltd.

South Tongda Rd., East Dist.

Jinzhou

052260 Hebei P.R. China

Scope:

Sites included:

Shijiazhuang Hongray Group Co., Ltd.

South Tongda Rd., East Dist., Jinzhou, 052260 Hebei, China

Distribution of Patient Examination Gloves

Syntex Healthcare Products Co., Ltd. No.1 Fanjiazhuang Industrial Zone, Xinji City, 052360, Hebei, China

Manufacture of Patient Examination Gloves

Grand Work Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, 050000, Hebei, China

Manufacture of Patient Examination Gloves

Certification Body



Date: 2020-04-16





Doc. 2/3, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

SX 60148697 0001

16801058 009

Organization:

Report No.:

Shijiazhuang Hongray

Group Co., Ltd.

South Tongda Rd., East Dist.

Jinzhou

052260 Hebei P.R. China

Scope:

Sites included:

Shijiazhuang Jiahe Plastic Glove Co., Ltd

Western Jiafeng Road, Mining Area, Shijiazhuang,

050100, Hebei, China

Manufacture of Patient Examination Gloves

Ever Light Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, Shijiazhuang,

050000, Hebei, China

Manufacture of Patient Examination Gloves

Better Care Plastic Technology Co., Ltd.

Fuqian Xi Road, West district of Shenze Industrial Base,

Shenze County, 050000, Hebei, China

Manufacture of Patient Examination Gloves

Certification Body



Date: 2020-04-16





Doc. 3/3, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

SX 60148697 0001

16801058 009

Organization:

Report No.:

Shijiazhuang Hongray

Group Co., Ltd. South Tongda Rd., East Dist.

Jinzhou

052260 Hebei P.R. China

Scope:

Sites included:

Hong Di Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, 050000, Hebei, China

Manufacture of Patient Examination Gloves

Shanxi Hongjin Plastic Technology Co., LTD

Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,

Linfen City, 042300, Shanxi, China

Manufacture of Patient Examination Gloves

Certification Body



Date: 2020-04-16





Business Stream Products Certification Department

Precisely Right.

Contact

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shijiazhuang Hongray Group Co., Ltd. South Tongda Rd., East Dist. Jinzhou 052260 HEBEI P.R. CHINA

Application for : QMS

Certificate No. : SX 60148697 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the new certificate No. SX 60148697 0001 replacing the previous certificate.

Kind regards

Certification body

Jing Znang

Test sample: no, documentation available

Tel. +49 911 655-5225 Mail service@de.tuv.com

Date April 16, 2020

TÜV Rheinland LGA Products GmbH

Tillystraße 2 90431 Nürnberg

Tel. +49 911 655-5225 Fax +49 911 655-5226 Mail service@de.tuv.com Web www.tuv.com/safety

Board of Management

Dipl.-Ing. Jörg Mähler, Spokesman

Dipl.-Kfm. Dr. Jörg Schlösser

Chairman of the Supervisory Board

Dipl.-Ing. Ralf Scheller

Nuremberg HRB 26013 VAT No.: DE 811835490

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Certificate

Standard ISO 9001:2015

Certificate Registr. No. 01 100 1732303

Certificate Holder: Shijiazhuang Hongray Group Co., Ltd.

Unified Social Credit Code: 91130100728799919R Registration Address: South Tongda Rd., East Dist.,

Jinzhou City, 052260 Hebei, P. R. China Operation Address: same as above

including the locations according to annex

Scope: Manufacture and Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the

requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-04-10 until 2020-10-19.

It remains valid subject to satisfactory surveillance audits.

First certification 2017

This certificate information can be searched on CNCA official

website http://www.cnca.gov.cn

2020-04-14

TÜV Rheinland Cert GmbH Am Grauen Stein \cdot 51105 Köln







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Annex to certificate

Standard ISO 9001:2015

Certificate Registr. No. **01 100 1732303**

No.	Location	Scope
/01	Shijiazhuang Hongray Group Co., Ltd. Unified Social Credit Code: 91130100728799919R Registration Address: South Tongda Rd., East Dist., Jinzhou City, 052260 Hebei, P. R. China Operation Address: same as above	Distribution of Patient Examination Gloves
/02	Syntex Healthcare Products Co., Ltd. Unified Social Credit Code: 91130181734364356G Registration Address: Southern No. 307 National Highway Rd., Western Fanjiazhuang Village, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/03	Grand Work Plastic Products Co., Ltd. Unified Social Credit Code: 91130100752433415G Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

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Annex to certificate

Standard ISO 9001:2015

Certificate Registr. No. 01 100 1732303

/06 Shijiazhuang Jiahe Plastic Glove Co., Ltd. Manufacture and Distribution of Patient

Unified Social Credit Code: 91130107563240147C

Registration Address: Northern Jiandi Village, Western Jiafeng Road, Mining Area, Shijiazhuang City, 050100 Hebei,

P. R. China

Operation Address: same as above

/07 JinZhou XinRui Plastic Products Co., Ltd.

> Unified Social Credit Code: 911301835795985148

Registration Address: South Tongda Rd., East Dist., Jinzhou City, 052260 Hebei,

P. R. China

Operation Address: same as above

/08 Purtech Cleanroom Products Co., Ltd.

> Unified Social Credit Code: 91130181777701957N

Registration Address: Fanjiazhuang Industrial Zone, Xinji City, 052360 Hebei,

P. R. China

Operation Address: same as above

/09 Ever Light Plastic Products Co., Ltd.

Unified Social Credit Code:

91130100784064765D

Registration Address: Donggao Industrial

Zone, Zanhuang, 050000 Hebei,

P. R. China

Operation Address: same as above

Examination Gloves

Manufacture and Distribution of Patient

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Annex to certificate

Standard ISO 9001:2015

Certificate Registr. No. 01 100 1732303

/10 Better Care Plastic Technology Co., Ltd.

Unified Social Credit Code: 911301286920575093

Registration Address: Shenze Industrial Base (Fugian Xi Road), Shenze County,

050000 Hebei, P. R. China

Operation Address: same as above

/11 Shijiazhuang Hongzan Plastic

Technology Co., Ltd. Unified Social Credit Code: 91130129567387090Y

Registration Address: Donggao Industrial

Zone, Zanhuang, 050000 Hebei,

P. R. China

Operation Address: same as above

/12 Shanxi Hongjin Plastic Technology

Co., Ltd.

Unified Social Credit Code: 91141030MA0HDY6R5D

Registration Address: Coal Bed Gas Industrial Zone, Qu'e Town, Daning County, Linfen City, 042300 Shanxi,

P. R. China

Operation Address: same as above

Manufacture and Distribution of Patient

Examination Gloves

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Examination Gloves

2020-04-14

TÜV Rheinland Cert GmbH Am Grauen Stein · 51105 Köln

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EC Declaration of Conformity

Manufacturer:

Shijiazhuang Hongray Group Co., Ltd. South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, China.

We, the manufacturer, herewith declare that the products

Disposable Vinyl/Nitrile Blend Examination Gloves
With the size of XS, S, M, L, XL and XXL

UMDNS-Code: 11-882

UDI:

Meet the provisions of MDR 2017/745 EU which apply to them.

The medical device has been assigned to class I according to Annex VIII of the MDR

 (ϵ)

2017/745 EU.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, EN ISO 14971:2012, EN ISO 13485:2016.

The glove is a disposable non-sterile device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

The product concerned has been manufactured under a quality management system according to Annex IX of MDR 2017/745 EU.

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/745 EU.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

Legally binding signature, Function

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

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, Ching

Jinzhou China 2020-05-10

Place, date

EC Declaration of Conformity

CE TECHNICAL DOCUMENTATION REVIEW REPORT

Company Name: Shijiazhuang Hongray Group Co. Ltd.

Address: South Tongda Road, East district, Jinzhou City, Hebei, 052260,

China

Review Intention: Review the completeness of the Technical Documentation according

to the requirements of Medical Devices Directive 93/42/EEC Annex

VII & the Regulation (EU) 2017/745 Annex II and III

Product(s): Disposable Vinyl/Nitrile Blend Examination Gloves

Type(s) / Model(s): Powder Free / XS, S, M, L, XL, XXL

Classification: Class I

(According to Annex IX Section III 1.1 and 1.4 of the Medical Devices

Directive 93/42/EEC & Annex VIII Chapter III 4.1 rule 1 of Medical

Device Regulations 2017/745)

Review period: January 20, 2020

Review Result: During the examination of the Technical Documentation (No: HRG-

JSWJ-003, Revision: A, Dated 2020-01-15), no non-compliance

according to the requirements of Medical Devices Directive

93/42/EEC Annex VII & the Regulation (EU) 2017/745 Annex II and

III was detected.

Signature: Wy Min

Date: January 20, 2020

Regulatory Authority

SHIJIAZHUANG HONGRAY GROUP

South Tongda Rd., East Dist. Jinzhou City, Hebei, 052260, China

SPECIFICATION FOR VINYL/NITRILE BLEND EXAMINATION GLOVE

1.0 Product: Vinyl/Nitrile Blend, Powder Free, 9" length, for examination use

2.0 Dimensions:

Cina	Median Length	Median Width	Thickness (mm) (min)		
Size	(mm)	(mm)	Palm	Finger	
XS	240	75±5	0.08	0.08	
S	240	85±5	0.08	0.08	
M	240	95±5	0.08	0.08	
L	240	105±5	0.08	0.08	
XL	240	115±5	0.08	0.08	

3.0 Strength:

Force at break: 3.6N (Median)

4.0 Water Leakage Testing:

For exam gloves, according to ISO2859, G-I, Single Sampling Plan, AQL1.5

5.0 Powder Residues:

For powder free gloves, not more than 2mg per glove.

DOCUMENT NO.: PVC-014E

INITIALED DATE: 2005.04.12 REVISION DATE: 2020.01.06 REVISION TIMES: 7

Company Name: Shijiazhuang Hongray Group Co. Ltd.

Address: South Tongda Road, East district, Jinzhou City, Hebei, 052260, China

Test Date: Dec 06, 2019

Product Description: Disposable Vinyl/Nitrile Blend Examination Gloves

Size: XS, S, M, L, XL

Test Standards: EN 455-1:2000 Medical Gloves for Single Use-Part 1: Requirements

and Testing For Freedom from Holes

EN 455-2:2015 Medical Gloves for Single Use-Part 2: Requirements

and Testing For Physical Properties

EN 455-3:2015 Medical Gloves for Single Use-Part 3: Requirements

and Testing For Biological Evaluation Clause 4.4 & 4.6

Specification:

	Item	Criteria	Quantity and Acceptance Criteria	
Length (mm)		≥240mm	13 pieces, median	
		XS: ≤80	13 pieces, median	
		S:80±10	13 pieces, median	
Wi	dth (mm)	M: 95±10	13 pieces, median	
1117		L: 110±10	13 pieces, median	
		XL: ≥110	13 pieces, median	
Thickness	Middle Fingertip t ^f	4f/48> 0 0	12	
(mm)	Test piece t ^x	t ^f /t ^x ≥0.9	13 pieces	
Force at Brea	ak (N) (Before and	≥3.6N	13 pieces, median	
Aft	er Aging)	≥3.011	13 pieces, median	
Water tightness		G I AOI 15	200 pieces	
		G-I, AQL1.5	(Ac7, Re 8)	
F	Powder	EN 455-3 Clause 4.4	<2mg/glove	
L	abelling	EN 455-3 Clause 4.6	Conform to EN 455-3 Clause 4.6	

Notes:

- 1. Condition of sampling testing: Temperature: 23±2°C, Humidity: 50±5%
- 2. Specimen shall be conditioned at least 16 hours before testing.
- 3. Challenge testing condition: seven days at a temperature of $70\pm2^{\circ}$ C in an oven.

Test Results: Please refer to the follows

1. Dimensions and Physical Properties

Test Standard and Method: EN 455-2

Test Condition: 22℃, 51%

Tested by: Ma Huina

		Length	Thicl	kness (mm)	Palm	Force at B	reak (N)
Serial No.	Size	(mm)	Test Piece	Middle Fingertip	Width (mm)	Before Aging	After Aging
1	XS	242	0.08	0.08	76	3.8	3.8
2	XS	241	0.08	0.09	77	3.5	3.9
3	XS	242	0.08	0.08	76	3.6	3.6
4	XS	240	0.08	0.09	76	3.9	3.8
5	XS	240	0.08	0.09	75	3.7	3.8
6	XS	242	0.08	0.08	76	3.5	3.7
7	XS	245	0.08	0.08	76	3.8	3.6
8	XS	244	0.08	0.09	76	3.6	3.5
9	XS	242	0.08	0.09	76	3.5	3.8
10	XS	243	0.08	0.09	76	3.7	3.8
11	XS	240	0.08	0.09	75	3.6	3.7
12	XS	241	0.08	0.08	76	3.7	3.5
13	XS	243	0.08	0.09	75	3.8	3.9
Median	Value	242	0.08	0.08	76	3.8	3.8
Test R	esult			Pass			
1	S	240	0.08	0.09	86	3.8	3.7
2	S	241	0.08	0.09	86	3.9	3.8
3	S	242	0.08	0.09	85	3.9	3.9
4	S	241	0.08	0.08	86	3.7	3.6
5	S	240	0.08	0.09	86	3.6	3.8
6	S	242	0.08	0.09	86	3.8	3.4
7	S	242	0.08	0.09	86	3.7	3.8
8	S	244	0.08	0.08	85	3.7	3.8
9	S	241	0.08	0.09	86	4.0	3.9
10	S	240	0.08	0.09	86	3.8	3.6
11	S	241	0.08	0.09	86	3.7	3.7
12	S	244	0.08	0.08	86	3.6	3.8
13	S	242	0.08	0.09	86	3.8	3.6
Median	Value	241	0.08	0.09	86	3.8	3.8
Test Result Pass							

			Thicl	kness (mm)	Palm	Force at Break (N)	
Serial No.	Size	Length (mm)	Test Piece	Middle Fingertip	Width (mm)	Before Aging	After Aging
1	M	242	0.08	0.09	96	3.9	3.7
2	M	241	0.08	0.08	96	3.6	3.8
3	M	243	0.08	0.09	96	3.7	3.9
4	M	241	0.08	0.09	96	3.8	3.6
5	M	240	0.08	0.09	95	3.5	3.5
6	M	242	0.08	0.08	97	3.7	3.8
7	M	240	0.08	0.09	97	3.8	3.6
8	M	244	0.08	0.09	96	3.6	3.8
9	M	243	0.08	0.09	96	3.9	3.9
10	M	243	0.08	0.08	96	3.4	3.7
11	M	241	0.08	0.09	96	3.8	3.6
12	M	240	0.08	0.08	96	3.8	3.8
13	M	240	0.08	0.09	96	3.9	3.9
Median	Value	241	0.08	0.08	96	3.8	3.8
Test R	esult			Pass			
1	L	242	0.08	0.08	105	3.8	3.8
2	L	241	0.08	0.09	105	3.9	3.9
3	L	243	0.08	0.09	106	3.7	3.6
4	L	241	0.08	0.08	105	3.5	3.8
5	L	243	0.08	0.08	105	3.6	3.5
6	L	242	0.08	0.08	107	3.5	3.8
7	L	242	0.08	0.09	106	4.0	3.6
8	L	244	0.08	0.09	106	3.8	3.5
9	L	242	0.08	0.08	106	3.6	3.8
10	L	240	0.08	0.09	107	3.6	3.6
11	L	242	0.08	0.09	106	4.0	3.6
12	L	241	0.08	0.09	106	3.8	3.8
13	L	242	0.08	0.09	106	3.9	3.9
Median	Value	242	0.08	0.08	106	3.8	3.8
Test R	esult	Pass					
1	XL	244	0.08	0.09	117	3.9	3.9
2	XL	241	0.08	0.09	116	3.7	3.5
3	XL	243	0.08	0.09	116	3.7	3.8
4	XL	243	0.08	0.08	116	3.8	3.6

5	XL	243	0.08	0.09	115	3.8	3.5
6	XL	244	0.08	0.08	116	3.6	3.8
7	XL	242	0.08	0.09	116	3.8	3.6
8	XL	244	0.08	0.09	116	3.9	3.8
9	XL	243	0.08	0.08	116	3.5	3.8
10	XL	242	0.08	0.09	117	3.6	3.6
11	XL	243	0.08	0.09	117	3.8	3.9
12	XL	240	0.08	0.08	116	3.6	3.8
13	XL	242	0.08	0.09	116	4.0	3.7
Median	Value	243	0.08	0.09	116	3.8	3.8
Test R	Test Result Pass						

2. Watertightness test

Test Standard and Method: EN 455-1

Sample Size: ISO2859, Inspection Level: G-1, AQL=1.5, 200pcs (Ac=7, Re=8)

Tested by: An Lijuan Ma Huina

Size	Sample Count (pcs)	Pinhole (pcs)	Test Result
XS	200	2	Pass
S	200	2	Pass
M	200	1	Pass
L	200	2	Pass
XL	200	3	Pass

3. Powder and Labeling

Test Standard and Method: EN 455-3 clause 4.4 & 4.6

Sample Size: 5 pieces of gloves were sampled.

Tested by: Ma Huina

Size	Average Powder (mg/glove)	Labelling	Test Result
XS	0.40	Pass	Pass
S	0.41	Pass	Pass
M	0.43	Pass	Pass
L	0.45	Pass	Pass
XL	0.47	Pass	Pass

Conclusion:

The Disposable Vinyl/Nitrile Blend Examination Gloves met the test requirements EN 455-1, EN 455-2 and EN455-3 Clause 4.4 &4.6.

Signed By: Zhang Li

Quality Manager