

# SETINO®



## Vinyl / Nitrile Blended GLOVES



**EN  
455**



**FDA**



## Company Awards and Certifications





# PRODUCT DESCRIPTION AND PICTURES





The Vinyl/Nitrile Blend (Vitrile) gloves is compounded with PVC paste and Nitrile latex, and the finished product has the advantage of both PVC and Nitrile glove.

- Product name: Powder free Vitrile Examination Gloves
- Single use, non-sterile, no measuring, latex free
- Sizes: S, M, L, XL, XXL
- Colors: Blue, Purple Blue
- Structure: 5 fingers, beaded cuff for easy donning, ambidextrous
- Surface: Textured on fingers
- Donning feeling better than vinyl gloves
- Softer than vinyl gloves
- Easy donning with wet hands and easier donning than nitrile & vinyl gloves.
- The shelf life is longer than nitrile gloves.

Intended purpose: The examination gloves are disposable non-sterile devices intended for medical purpose that are worn on the examiner's hand and fingers to prevent contamination between patient and examiner.

• Pictures:



Size	Length (mm)	Width (mm)(mm)	Single glove weight (+/-0.2)	Carton gross weight	Barcode
S	240	80+/-10	5.5 g	6.4 kg	 5 991326 504219
M	240	95+/-10	6.0 g	6.9 kg	 5 991326 504226
L	240	105+/-10	6.5 g	7.1 kg	 5 991326 504233
XL	240	115+/-10	7.0 g	7.8 kg	 5 991326 504240



# DISPOSABLE VINYL/NITRILE BLEND GLOVES BOX DESIGN



235 x 115 x 65 mm





# 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: 2020-09-30  
Certificate Registration No.: SX 60151704 0001  
An audit was performed. Report No.: 16801058 009  
This Certificate is valid until: 2023-04-25

Certification Body



Date 2020-09-30



**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>

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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60151704 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 Jiahe Plastic Glove Co., Ltd.  
Western Jiafeng Road, Mining Area, Shijiazhuang,  
050100, Hebei, P.R. China

Manufacture of Patient Examination Gloves

Ever Light Plastic Products Co., Ltd.  
Donggao Industrial Zone, Zanhuang, Shijiazhuang,  
050000, Hebei, P.R. 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, P.R. China

Manufacture of Patient Examination Gloves

**Certification Body**



**Date:** 2020-09-30



**Wenxiang Zhang**



# EU DECLARATION OF CONFORMITY

*Manufacturer:*

Shijiazhuang Hongray Group Co., Ltd.  
South Tongda Rd., East Dist. Jinzhou, 052260  
Hebei, China  
Tel.: +86-311-83610904  
Fax: +86-311-83610904

*Distributor:*

Setino Hungary Kft.  
Száva 4/B 1107  
Budapest, Hungary  
Tel.: +36-1-349-1053

under its sole responsibility declares, that the personal protective equipment specified below:

**Disposable Vinyl / Nitrile Blend Glove**  
**VNPF2001-2005**  
**SETINO CODE: VN-3**

was classified in category III. - PPE (EU) 2016/425 II. according to its annex  
EN ISO 374-1: 2016; EN ISO374-4:2019; EN ISO 374-5: 2016; EN ISO21 420:2020

EN ISO 374-5:2016



**VIRUS**

EN ISO 374-1:2016/Type B



**KPT**

The protective equipment complies with the requirements of Regulation 2016/425 (EU) and the harmonized European standards EN ISO 374-1: 2016, EN ISO 374-5: 2016, EN ISO374-4:2019, EN ISO21 420:2020 and identical to PPE covered by EU type examination (Module B); certificate number: 2777/15012-01/E00-00.

Issuing certification body:

**SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland**  
**Notified Body: 2777**

According to module C2 for PPE, a conformity assessment procedure is carried out under the supervision of the notified body, supervising:

**SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland**  
**Notified Body: 2777**

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

2020.10.16.

Place, date



*[Handwritten Signature]*

Signature



# EC Declaration of Conformity

*Manufacturer:*

Shijiazhuang Hongray Group Co., Ltd.  
South Tongda Rd., East Dist. Jinzhou, 052260  
Hebei, China.  
Tel: +86-311-83610904  
Fax: +86-311-83610904

*whose single Authorized Representative:*

Caretechion GmbH  
Niederrheinstr. 71, 40474 Düsseldorf,  
Germany  
DIMDI Code: DE/0000048026  
Tel/Fax: 0211 3003 6618  
Email: info@caretechion.de

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: 11882**

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 2017/745 EU.



Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015,  
EN455-4:2009, 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.

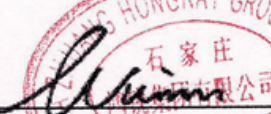
Declare the conformity of their products by issuing the EU declaration of conformity referred to  
in Article 19 after drawing up the technical documentation set out in Annexes II and III.

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

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, China.**

Jinzhou China 2020-05-10  
Place, date

QD:   
Legally binding signature, Function





# EU Type-Examination Certificate

## Certificate number: 2777/15012-01/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:**

VNPF2001-2005

**Description:**

Disposable Vinyl/Nitrile Blend Examination Gloves.

Colour: Blue, Green, Black.

**Sizes:**

XS(6)-XL(10)

**Classification:**

EN ISO 374-1:2016+A1:2018/ Type B	Level	EN ISO 374-4:2019 Degradation %
40% Sodium hydroxide (K)	6	-1.2
30% Hydrogen peroxide (P)	6	2.7
37% Formaldehyde (T)	6	-8.1

**EN ISO 374-5:2016**

Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

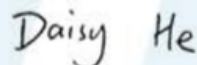
**Standards/Technical specifications applied:**

EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

**Technical reports/Approval documents:**

SATRA: CHT0298236/2021, CHM0298451/2022/LH/A, CHM0298451/2022/LH/B, CHM0298451/2022/EN/C

Signed on behalf of SATRA:



Daisy He



Quincey Brown

**Date first issued: 08/09/2020****Date of issue: 08/09/2020****Expiry date: 08/09/2025**



**RESULTS:**

Sample: Disposable Vinyl/Nitrile Blend Examination Gloves

**Table 1: Results for EN 455-1:2000**

Clause	Tests	Size	Requirements	No. of non-compliers Allowed (pieces)	Number Tested (pieces)	Actual No. of non-compliers Found (pieces)	Inferred Results
4 5	Freedom from holes	M	Shall not leak	7	200	0	Passed

**Table 2: Results for EN 455-2:2015 Clauses 4-5**

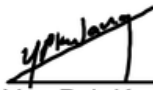
Clause	Tests	Size	Requirements (Median)	Number Tested (pieces)	Results (Median)	Inferred Results
4	Dimensions a) Length (mm)	XS	≥ 240	13	245	Passed
		S	≥ 240	13	245	Passed
		M	≥ 240	13	248	Passed
		L	≥ 240	13	247	Passed
		XL	≥ 240	13	248	Passed
		XXL	≥ 240	13	259	Passed
	b) Width (mm)	XS	≤ 80	13	77	Passed
		S	80 ± 10	13	86	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	114	Passed
		XXL	≥ 110	13	123	Passed
5	Strength a) Force at break (N)	M	For vinyl examination gloves: ≥ 3.6	13	4.4	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	M	For vinyl examination gloves: ≥ 3.6	13	4.2	Passed

**Table 3: Results for EN 455-3:2015 Clause 4.4**

Clause	Tests	Size	Requirements	Result	Inferred Results
4.4 5.2	Powder-free gloves	L	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.16 mg per glove	Passed

**REMARK:**

1. Lot number was not provided by client.

  
Yeo Poh Kwang  
Associate Engineer

  
Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

**APPENDIX:**



Photo: Disposable Vinyl/Nitrile Blend Examination Gloves





# Testing Report

**Company Name:** Grand Work Plastic Products Co., Ltd  
**Address:** Donggao Industrial Zone, Zhanhuang, Hebei, 050000, China  
**Test Date:** Dec 06, 2019  
**Product Description:** Powder Free Vinyl/Nitrile Blended 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)		$\geq 240\text{mm}$	13 pieces, median
Width (mm)		XS: $\leq 80$	13 pieces, median
		S: $80 \pm 10$	13 pieces, median
		M: $95 \pm 10$	13 pieces, median
		L: $110 \pm 10$	13 pieces, median
		XL: $\geq 110$	13 pieces, median
Thickness (mm)	Middle Fingertip $t^f$	$t^f/t^x \geq 0.9$	13 pieces
	Test piece $t^x$		
Force at Break (N) (Before and After Aging)		$\geq 3.6\text{N}$	13 pieces, median
Water tightness		G-I, AQL1.5	200 pieces (Ac7, Re 8)
Powder		EN 455-3 Clause 4.4	<2mg /glove
Labelling		EN 455-3 Clause 4.6	Conform to EN 455-3 Clause 4.6
Notes:			
1. Condition of sampling testing: Temperature: $23 \pm 2^\circ\text{C}$ , Humidity: $50 \pm 5\%$			
2. Specimen shall be conditioned at least 16 hours before testing.			
3. Challenge testing condition: seven days at a temperature of $70 \pm 2^\circ\text{C}$ in an oven.			

Test Results: Please refer to the follows