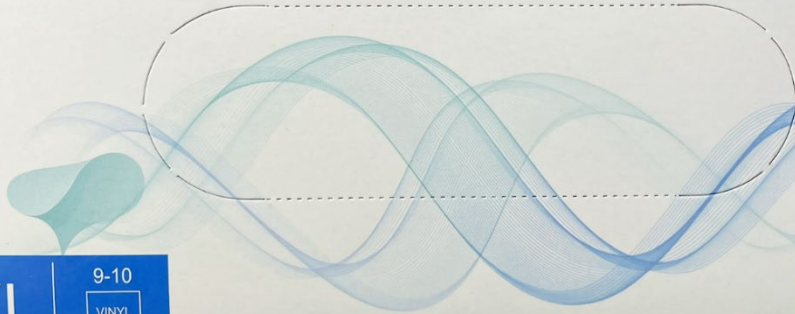


SETINO®

EINWEG VINYL-PRÜFHANDSCHUHE/
DISPOSABLE VINYL EXAMINATION GLOVES



XL

9-10

VINYL

NICHT STERIL/
NON-STERILE

PUDERFREI/
POWDER-FREE

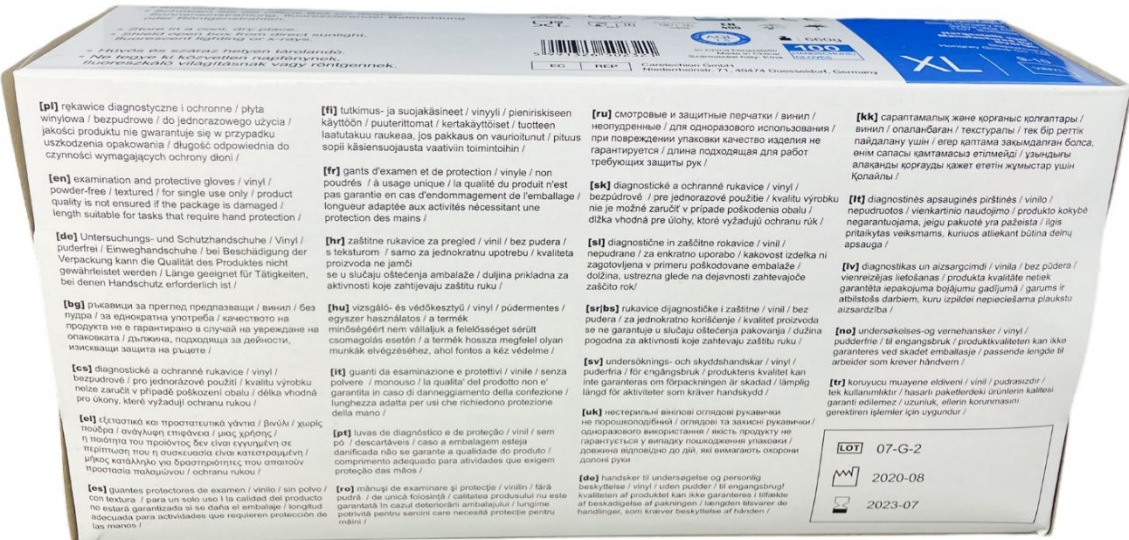
BEIDHÄNDIG/
AMBIDEXTROUS

EINWEG/
SINGLE USE

CE

100
HANDSCHUHE/
GLOVES





[pl] rękawice diagnostyczne i ochronne / płyta winyłowa / bezpydrowe / do jednorazowego użycia / jeżeli produkt nie gwarantuje się w przypadku uszkodzenia opakowania / długość odpowiadna do czynności wymagających ochrony dłoni /

[en] examination and protective gloves / vinyl / powder-free / textured / for single use only / product quality is not ensured if the package is damaged / length suitable for tasks that require hand protection /

[de] Untersuchungs- und Schutzhandschuhe / Vinyl / puderfrei / Einweghandschuhe / bei Beschädigung der Verpackung kann die Qualität des Produktes nicht gewährleistet werden / Länge geeignet für Tätigkeiten, bei denen Handschutz erforderlich ist /

[fr] gants d'examen et de protection / vinyle / non poudrés / à usage unique / la qualité du produit n'est pas garantie en cas d'endommagement de l'emballage / longueur adaptée aux activités nécessitant une protection des mains /

[it] guanti da esame e protettivi / vinile / senza polvere / monouso / la qualità del prodotto non è garantita in caso di danneggiamento della confezione / lunghezza adatta per usi che richiedono protezione della mano /

[ru] смотровые и защитные перчатки / винил / неопудренные / для однократного использования / при повреждении упаковки качество изделия не гарантируется / длина подходящая для работ требующих защиты рук /

[uk] діагностичні а охранные рукавички / вініл / безпудрові / для одноразового використання / при пошкодженні упаковки якість виробу не гарантується / довжина відповідає для робіт, які потребують захисту рук /

[lv] diagnostiskās un aizsargājošās rokassaites / vinils / bez pudrēm / lietošanai vienreizēji / produkta kvalitāte netiek garantēta, ja iepakojuma bojājuma gadījumā / garums ir atbilstošs darbiem, kuriem nepieciešama plaukstu aizsardzība /

[no] undersøknings- og beskydshandsker / vinyl / puderfrie / til engangsbruk / produktkvaliteten kan ikke garanteres ved skadet emballasje / passende lengde til arbeider som krever håndvern /

[tr] koruyucu muayene eldiveni / vinil / pudrasızdır / tek kullanımlıktır / hasarı pakettedeki ürünün kalitesi garanti edilemez / uzunluk, elleri korumaları gerektiren işlemler için uygundur /

[es] guantes protectores de examen / vinilo / sin polvo / con textura / para un solo uso / la calidad del producto no estará garantizada si se daña el embalaje / longitud adecuada para actividades que requieren protección de las manos /

[pt] luvas de diagnóstico e de proteção / vinil / sem pó / descartáveis / caso a embalagem esteja danificada não se garante a qualidade do produto / comprimento adequado para atividades que exigem proteção das mãos /

[ca] manilles de examen i de protecció / vinil / fara pols / de descartar / si s'ha danyat l'embalatge no es garante la qualitat del producte / longitud adequada per a activitats que necessiten protecció de les mans /

[da] undersøgnings- og beskydshandsker / vinyl / puderfrie / til engangsbrug / produktkvaliteten kan ikke garanteres i tilfælde af beskadigelse af pakningen / længden svarer de håndteringer, som kræver beskyttelse af hænderne /

LOT 07-G-2

2020-08

2023-07

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>

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 · 51105 Köln

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.com

We, the manufacturer, herewith declare that the products

Disposable Vinyl Examination Glove
UMDNS-Code: 11-882

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.



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

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.

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 2020-04-01
Place, date

GM:  *Manager*
Legally binding signature, Function

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): Examination Vinyl Gloves

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

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: June 06, 2019

Review Result: During the examination of the Technical Documentation (No: HRG-JSWJ-001, Revision: C, Dated 2019-05-10), 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: Wu Min

Date: June 06, 2019

Regulatory Authority



SGS

VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE

No.: SHHL1602007861MD-02C
Product Name: DISPOSABLE VINYL GLOVE
Style No: XS,S,M,L,XL
Applicant: SHIJIAZHUANG HONGRAY GROUP CO.,LTD
SOUTH TONGDA RD.,EAST DIST. JINZHOU CITY, HEBEI,
052260, CHINA
Manufacturer: SHIJIAZHUANG HONGRAY GROUP CO.,LTD
SOUTH TONGDA RD.,EAST DIST. JINZHOU CITY, HEBEI,
052260, CHINA
Sufficient samples of the product have been tested and found to be in conformity with
Test Standard: EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE-
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM
HOLES
EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE-
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL
PROPERTIE
EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE-
PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL
EVALUATION CLAUSE 4.4 & 4.6
as shown in the
Test Report Number(s): SHHL1602007861MD-02, SHHL1602007862MD-02
SHHL1602007863MD-02

This verification is only valid for the equipment and configuration described, and in conjunction with the test data detailed. It contains the result of the single examination of the subject being in hand and does not represent any universally valid decision concerning the quality of any subject of the current production.

Donna Gu
CRS/Hardline SBU Section Head
SGS-CSTC Standards Technical Services Co., Ltd.

Apr 12, 2016

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Test Report

No.: SHHL1602007863MD-02

Date: APR. 08,2016

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Test Conducted:

- EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample : 200 Pieces
 The type of gloves : examination/procedure gloves
 Manufacturing batch code : /
 Batch size : /
 Sample size : XS, S, M, L, XL
 Number of non-conforming gloves : None
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing		# 1&2

- EN 455-2: 2015 Medical gloves for single use – part 2: Requirements and testing for physical propertie

Number of test sample : 91 Pieces
 Type : examination/procedure gloves
 The manufacturing batch code : /
 Size : XS, S, M, L, XL
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#1&4
7	Labeling	Pass	/



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Test Report

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3. EN 455-3: 2015 Medical gloves for single use—Part 3: Requirements and testing for biological evaluation

Number of test sample : 5 Pieces
 Finishes of gloves : Powdered-free gloves other than surgeon's gloves
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1, 5&6
4.6	Labeling	Pass	/

Note:

- As per client's declare, these gloves (four size: XS, S, M, L, XL) only size different, the material is the same, and only the glove of size M was tested.
- See result 1.
- See result 2.
- See result 3.
- Test according to EN ISO 21171-2006.
- The powder of sample was 0.4mg < 2mg.



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Test Results:

1. Watertightness test for detection of holes

Sample Quantity: 200pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

2. Dimensions

Sample Quantity: 65pcs

Size	XS												
Length(mm)	243	244	243	244	242	242	245	244	243	242	244	243	242
Width(mm)	78	77	76	77	78	77	76	78	78	76	77	76	77

Median value:

Length (mm): 243
Width (mm): 77

Size	S												
Length(mm)	246	245	246	245	245	247	246	245	244	243	244	242	245
Width(mm)	88	87	86	85	85	86	87	88	87	85	86	85	86

Median value:

Length (mm): 245
Width (mm): 86

Size	M												
Length(mm)	248	248	249	248	247	248	249	249	250	248	247	246	247
Width(mm)	96	95	97	96	97	96	95	96	95	97	96	95	96

Median value:

Length (mm): 248
Width (mm): 96

Size	L												
Length(mm)	243	242	243	242	242	242	243	244	243	244	243	242	243
Width(mm)	106	105	106	104	105	106	107	106	105	106	107	105	104

Median value:

Length (mm): 243
Width (mm): 106



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Size	XL												
Length(mm)	255	252	254	252	254	253	252	254	253	252	253	254	253
Width(mm)	117	118	115	117	116	118	117	116	115	116	117	118	117

Median value:

Length (mm): 253

Width (mm): 117

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥250	67±4
5.5	≥250	72±4
6	≥260	77±5
6.5	≥260	83±5
7	≥270	89±5
7.5	≥270	95±5
8	≥270	102±6
8.5	≥280	108±6
9	≥280	114±6
9.5	≥280	121±6

Table 2 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		≥110



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Testing Center Harbin

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3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	4.50	4.84	4.57	4.49	4.91	4.48	4.45	4.37	4.74	4.78	4.89	4.80	4.65
Force at break after challenge testing(N)	4.75	4.61	4.54	4.79	4.82	4.76	4.75	4.82	4.38	4.61	4.78	4.69	4.65

Median value:

Force at break during shelf life (N): 4.65

Force at break after challenge testing (N): 4.75

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b) c)	
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).. c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			

Remark:

- The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.



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Sample Photo:

Received sample (size XS)



Received sample (size S)



Received sample (size M)



Received sample (size L)



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