

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: 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 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.

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

EC Declaration of Conformity

GM: 
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): 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: Wu Min

Date: January 20, 2020

Regulatory Authority

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>

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 Fanjiashuang 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



Jing Zhang

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 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



Jing Zhang

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:

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

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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

Contact

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

Date April 16, 2020

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 Zhang

Test sample: no, documentation available

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

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

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

Annex to certificate

Standard **ISO 9001:2015**

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

- | | | |
|-----|--|---|
| /06 | Shijiazhuang Jiahe Plastic Glove Co., Ltd.
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 | Manufacture and Distribution of Patient
Examination Gloves |
| /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 | Manufacture and Distribution of Patient
Examination Gloves |
| /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 | Manufacture and Distribution of Patient
Examination Gloves |
| /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 | Manufacture and Distribution of Patient
Examination Gloves |

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 (Fuqian Xi Road), Shenze County,
050000 Hebei, P. R. China
Operation Address: same as above | Manufacture and Distribution of Patient
Examination Gloves |
| /11 | Shijiazhuang Hongzan Plastic
Technology Co., Ltd.
Unified Social Credit Code:
91130129567387090Y
Registration Address: Donggao Industrial
Zone, Zanhuan, 050000 Hebei,
P. R. China
Operation Address: same as above | Manufacture and Distribution of Patient
Examination Gloves |
| /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 |

2020-04-14



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 3 of 3