

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 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

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

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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



Precisely Right.

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

A handwritten signature in blue ink, appearing to read 'Jing Zhang'.

Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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Chairman of the
Supervisory Board

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Ralf Scheller

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