

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

Scope: Design and Development, Manufacture and Distribution of Patient  
Examination Gloves

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190131115 110  
Effective date: 2021-04-15  
Expiry date: 2024-04-14  
Issue date: 2021-04-13

  
Jing Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

## Quality Management System EN ISO 13485:2016

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West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Zhonghong Pulin Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Distribution of Patient Examination Gloves
/02	c/o Minghao Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

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## Quality Management System EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

The scope of certification also covers the following:

- |     |   |   |
|-----|---|---|
| /03 | c/o The First Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd.<br>Pachigang Industrial Park, Luannan County, Tangshan City, 063502 Hebei, P.R. China               | Design and Development, Manufacture of Patient Examination Gloves |
| /04 | c/o The Fifth Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd.<br>South Peituozi Village, Sigezhuang Town, Luannan County, Tangshan City, 063503 Hebei, P.R. China | Design and Development, Manufacture of Patient Examination Gloves |

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TÜV Rheinland LGA Products GmbH  
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TÜV Rheinland LGA Products GmbH • 51105 Köln

Zhonghong Pulin Medical Products Co., Ltd.  
West Industrial Park, Luannan County, Tangshan City,  
063500 Hebei, P.R. China

Contact

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Date April 13, 2021

**Application for: QMS**

Certificate No. : SX 2059694-1

Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2059694-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

  
Jing Zhang  
Certification body

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LGA Products GmbH

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Germany

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90431 Nuremberg

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