



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 040345 0018 Rev. 03

**Holder of Certificate:** **Suzhou Colour-way New Material Co., Ltd.**

No. 20, Anmin Road, Huangdai Town  
Xiangcheng District  
215152 Suzhou City, Jiangsu Province  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

**Design and Development, Production and Distribution of Rubber Surgical Gloves, Rubber Examination Gloves, Natural Latex Rubber Condoms, Polyurethane Condoms, Radiation Attenuating Rubber Surgical Gloves**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 040345 0018 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5 040345 0018 Rev. 03)

**Report No.:** SH25003201

**Valid from:** 2026-02-01  
**Valid until:** 2029-01-31

**Date:** 2025-12-01

Christoph Dicks  
Head of Certification/Notified Body



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**Applied Standard(s):**

ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):**

**Suzhou Colour-way New Material Co., Ltd.**

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Suzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Distribution of  
Rubber Surgical Gloves, Rubber Examination Gloves,  
Natural Latex Rubber Condoms, Polyurethane Condoms,  
Radiation Attenuating Rubber Surgical Gloves

**Suzhou Colour-way New Material Co., Ltd.**

NO.51,Wangzhuang Road, Huangdai Town, Xiangcheng District,  
215152 Suzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF  
CHINA

Production of Rubber Surgical Gloves,  
Rubber Examination Gloves,  
Natural Latex Rubber Condoms, Polyurethane Condoms,  
Radiation Attenuating Rubber Surgical Gloves