



Certificate

No. Q5 040345 0018 Rev. 01

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

Facility(ies): 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

Suzhou Colour-way New Material Co., Ltd.

Huashi Industry Park, 214421 Jiangyin, 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

Applied Standard(s):

EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016)

DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.:

SH1903224

Valid from:

2020-02-01

Valid until:

2023-01-31

Date,

2020-01-09

Christoph Dicks

Head of Certification/Notified Body