



EC Certificate

Production Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex V (Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 040345 0016 Rev. 03

Manufacturer 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

Sterile Rubber Examination Gloves **Product**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1903224

Category(ies):

Date.

Valid from: 2020-01-09

Valid until: 2024-02-25

2020-01-09

Christoph Dicks Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123