



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 040345 0019 Rev. 00**

**Manufacturer:** Suzhou Colour-way Enterprise  
Development Co., Ltd.

Dongqiao Industrial Area  
215152 Suzhou/ Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, GERMANY

**Product Category(ies):** Rubber Surgical Gloves, Natural Latex Rubber  
Condoms, Radiation Attenuating Rubber Surgical  
Gloves, Polyurethane Condoms

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** SH1903223

**Valid from:** 2019-04-16

**Valid until:** 2024-02-25

**Date,** 2019-04-16

Stefan Preiß

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A4 / 07.17



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## Facility(ies):

Suzhou Colour-way Enterprise Development Co., Ltd.  
 Dongqiao Industrial Area, 215152 Suzhou/ Jiangsu, PEOPLE'S  
 REPUBLIC OF CHINA

Suzhou Colour-way Enterprise Development Co., Ltd.  
 Huashi Industry Park, 214421 Jiangyin, PEOPLE'S REPUBLIC OF  
 CHINA

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