



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 13 12 40345 015

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):** Condom,
Surgical Gloves

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.: SH13032EXT01

Valid from: 2014-02-26

Valid until: 2019-02-25



Date, 2014-01-16

Hans-Heiner Junker

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

Page 1 of 2



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 13 12 40345 015**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