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. 01

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

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.: SH1903224

Digitally signed by Guțan Ghenadie
Date: 2021.02.09 15:07:27 EET
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Location: Moldova

Valid from: 2020-01-09
Valid until: 2024-02-25

Date, 2020-01-09

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

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