

Declaration of Conformity

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
European Representative: Shanghai International Holding Corp. GmbH (Europe)
Product Name: Eiffestrasse 80, 20537 Hamburg, Germany
Rubber Surgical Gloves
Object of the declaration: Specific ID: Powdered, Textured, Sterile, Size: 7#, 7.5#, 8#, 8.5#
Lot No.: 200401
Number of products: 55 thousand pairs
UMDNS Code: 11883

Classification (MDD, Annex IX): IIa, rule 7

Conformity Assessment Route: Annex II.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339, München, Germany
Identification number: CE0123
(EC) Certificate(s): G1 040345 0019 Rev.01
Expire date of the Certificate: 2024/02/25
Start of CE Marking: 1999/02/10
Place, Date of Issue: Suzhou City, 2020-3-26

Signature: _____
Name: Mr. Yongping Xu
Position: General Manager

