Declaration of Conformity

Manufacturer	Fitone Latex Products Co., Ltd. Guangdong
Address	No.5 Tongyi Road, Lingbei Industrial Zone, Suixi, 524338 Zhanjiang, Guangdong, PEOPLE'S REPUBLIC OF CHINA
European Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg Germany

Product Single-use Sterile Latex Surgical Gloves

Model Code Size: 6;6.5;7;7.5;8;8.5;9

Classification (MDD, Annex Ⅸ):Classified to IIa in accordance to Rule 7， 2.3 of MDD 93/42/EEC Annex IX

Conformity Assessment Procedure: Directive 93/42/EEC on Medical Devices Annex Ⅴ.3

UMDNS-Code:11883

We here with declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.The manufacturer is exclusively responsible for the DoC.

DIRECTIVES

General Applicable Directives:
Medical Device Directive: Council Directive 93/42/EEC concerning medical devices (MDD 93/42/EEC).

Standards Applied:
Harmonized standards published in the official journal of the European communities applicable to this product.

Notified Body: TüV SüD Product Service GmbH, Ridlerstrasse.65, 80339 Munich, Germany

NB Identification Number: CE0123

EC Certificate: G 2 087066 0008 Rev.00, Valid until:2024-03-11

Start of CE Marking: 2014-03-12

Place, Date of issue: Zhanjiang, 2020-12-31

Vice President Signature _____

广东通乳胶制品集团有限公司 质量管理部

Digitally signed by Guțan Ghenadie
Date: 2021.12.23 12:49:26 EET
Reason: MoldSign Signature
Location: Moldova