

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)
Address	Eiffestrasse 80, 20537 Hamburg Germany.
Product Name	Single-use medical latex examination gloves
Model Code	Size:XL/L/M/S/XS
Classification	Classified to I in accordance to Rule 4, 4.1 of MDR (EU)2017/745 Annex VIII
Conformity Assessment Route:	MDR (EU)2017/745 in Article 52(7)
UMDNS Code	11882
EMDN Code	T010201
SRN Code	CN-MF-000012805

We herewith declare that the above mentioned products meet the provisions of the following Regulation(EU) and Standards. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the DoC.

REGULATION

General applicable regulation:
REGULATION (EU)2017/745 on Medical Devices.

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

Place, date of issue: Zhanjiang 2021.10.01

Vice president Signature 

