

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 Shanghai International Holding Corp. GmbH (Europe)
Representative Eiffestrasse 80, 20537 Hamburg Germany

Product Medical Nitrile Examination Gloves
Product standard number EN455
Model code size:XS/S/M/L/XL
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

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 2021.03.01

Vice president Signature

