EU Declaration of Conformity

In according to Medical Device Regulation (EU) 2017/745

Doc.No.:FN-QS9.3-GL-MD-FN-260701 Rev.00

Manufacturer:	**Finess Healthcare Group Co.,Ltd** 6th Floor, Building C, Jiaotong BOBO Internati onal, No.221 Yongfeng West Road, Haishu District, Ningbo, 315000, China	SRN No.:	CN-MF-000004124
European Representative:	**SUNGO Europe B.V.** Fascinatio Boulevard 522, Unit 1.7, 2909VA C apelle aan den IJssel, The Netherlands	SRN No.:	NL-AR-000000247
Product Name:	Nitrile Examination Gloves		
Model Number:	With reference to Annex I		
Basic UDI-DI:	697391169GL010102KE		

Classification (MDR, Annex VIII): Class I Non sterile,Rule 1
Conformity Assessment Route: Article 19+Annex II+Annex III

We herewith declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.The products above are in conformity with the Medical Device Regulation (EU) 2017/745.All supporting documentation is retained under the premises of the manufacturer.

Harmonized Standards:
EN 455-1:2020+A2:2024 EN 455-2:2024 EN 455-3:2023 EN ISO 10993-10:2023
EN ISO 15223-1:2021/A1:2025

General Applicable Regulation:
Medical Device Regulation (EU) 2017/745 and other applicable EU standards and MDCG Guidance.

EU Declaration of Conformity

In according to the Regulation (EU) 2016/425 for Personal Protective Equipment

Description:	Disposable Nitrile Powder-Free Examination Glove
Specification:	Size XS,Size S,Size M,Size L,Size XL
Color:	Blue
Finess Item no.:	With reference to Annex I
Manufacturer	**Finess Healthcare Group Co.,Ltd** 6th Floor, Building C, Jiaotong BOBO International, No. 221 Yongfeng West Road, Haishu District, Ningbo, 315000, China
Authorized Representative	**SUNGO Europe B.V.** Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
This declaration of conformity is issued under the sole responsibility of the Manufacturer.	
Object of the Declaration	Nitirle Examination Gloves(Size XS,Size S,Size M,Size L,Size XL) Category III
Relevant regulation	Regulation(EU)2016/425 for personal protective equipment
Applied standards	EN ISO21420:2020:+A1:2024 EN ISO 374-2:2019 EN ISO374-4:2019 EN ISO374-5:2016 EN 16523-1:2015+A1:2018 EN ISO 374-1:2016+A1:2018 Type B

Notified body Satra Technology Europe Ltd,Bracetown Business Park, Clonee, Dublin 15 Dublin Ireland,
Notified Body number: 2777
Certificate No.:2777/27163-02/E00-00

The subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals(Module C2)under surveillance of the notified body SATRA Technology Europe Limited(CE2777).

Product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation(EU)2016/425 as a Category III product.

Annex I Model Information

No.	Finess REF Code	Glove Size	Packing Qty/box
1	FN-GL010102010102	Size XS	100pcs/box
2	FN-GL010102010203	Size S	100pcs/box
3	FN-GL010102010302	Size M	100pcs/box
4	FN-GL010102010404	Size L	100pcs/box
5	FN-GL010102010503	Size XL	100pcs/box

Place,Date of Issue: Ningbo,2026-07-03

Signature: 

Name: Ruby Fu Position: PRRC