



Declaration of Conformity

Doc.No.:FN-QS9.3-GL01-FN0101 Rev.00

Manufacturer:	Finess Healthcare Group Co.,Ltd No.1503 A1 Block,No.203 Lantian Road 315000 Ningbo PEOPLE'S REPUBLIC OF CHINA
European Representative:	ZOUSTECH S.L. Pso. Castellana,141-Planta 19, 28046 Madrid, SPAIN
Product Name	Nitrile Examination Gloves
Model Number:	FN-GL010102010304
UMDNS-Code:	11882

Classification (MDD, Annex IX): Class I Non Sterile Rule 5

Conformity Assessment Route: **Annex VII**

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.

Manufacturer takes full responsibility of the content of Declaration of Conformity.

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Harmonized Standards:

EN ISO13485:2016 EN ISO15223-1:2016 EN455-1:2000 EN455-2:2015
EN1041:2008+A1:2013 EN455-3:2015

Signature: *Michelle-Z*

Name:Michelle Zhang

Place& Date: Ningbo 2020-01-01

Position: Management Representative