

Declaration of Conformity

Manufacturer: **Tianchang City Anrui Medical Equipments Co., Ltd., Renhe Industrial District, 239331 Tianchang City, Anhui Province, People's Republic of China**

European Representative: **Shanghai International Medical Devices Consulting S.L. C/ Ancha N2 Mijas Costa, Malaga-Spain**

Product Name: **Latex Surgical Gloves**

Specification/Model: **Powder-Free Latex Surgical Gloves, Sizes 6#, 6.5#, 7#, 7.5#, 8#, 8.5#, 9#**

UMDNS Code: **11883**

Classification (MOD, Annex IX): **Ila, Rule 6**
Conformity Assessment Route: **Annex V.3**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Harmonised Standards. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical device" (MDD 93/42/EEC) including requirements according to MDR Article 120(3) on May 26th, 2021.

List of EU Harmonized Standards applicable for this product: EN455-1, EN455-2, EN455-3, EN455-4.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65, 80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): G2 088431 0002 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2015-03-03

Place, Date of Issue: Tianchang, 2021-08-15

Signature:

Name: Bi Wen Zhang

Position: General Manager

