

## 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**  
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Product Name: Latex Surgical Gloves  
Specification: 6#, 6.5#, 7#, 7.5#, 8#, 8.5#, 9#

UMDNS Code: 11883

Classification (MDD, 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: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015  
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD 93/42/EEC).

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: 2019-11-26

Place, Date of Issue: **Tianchang, 2019-11-26**

Signature:

Name: **Biwen Zhang**

Position: **General Manager**

