

# **Anhui Anyu Latex Products Co., Ltd**

## **Declaration of Conformity**

MANUFACTURER: ANHUI ANYU LATEX PRODUCTS CO., LTD.

ADDRESS: NO. 95 YUHE ROAD, BENGBU, ANHUI, CHINA

EUROPEAN REPRESENTATIVE: Shanghai International Trading Corp. GmbH (Hamburg)

ADDRESS: Eiffestrasse 80, 20537, Hamburg

PRODUCTS:

STERILE LATEX SURGICAL GLOVES (11883)

Powdered / Powder Free, Size: 6, 6.5, 7, 7.5, 8, 8.5, 9

UMDNS code: 11883

Classification (MDD, Annex IX): II a, rule 7

LATEX EXAMINATION GLOVES (11882)

Powdered/Powder Free, Size: L, M, S

UMDNS code: 11882

Classification (MDD, Annex IX): I sterile, rule 5

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 Standards. All supporting documentations are retained under the premises of the manufacturer.

### **DIRECTIVES**

Medical Device Directive: DIRECTIVE 93/42/EC on Medical Devices(MDD).

Standard Applied: See attached list of (Harmonized – EN) standards for which documented evidence of compliance can be provided.

Notified Body: TÜV SÜD Product Service GmbH  
Address: Ridlerstr. 65, 80339 MÜNchen, Germany  
Identification number: CE 0123  
(EC) Certificate(s): G2 087547 0009, Sterile Surgical Gloves,  
G2S 087457 0008, Sterile Examination Gloves  
Expire date of the Certificate: 2024-5-14  
Start of CE Marking: 2019-5-15  
Place, Date of Issue: 2019-5-17

Signature: \_\_\_\_\_

Name: Shi Mingyu

Position: General Manager

安徽安宇乳胶制品有限公司  
ANHUI ANYU LATEX  
PRODUCTS CO., LTD

