

Baoying County Fukang Medical Appliance Co.Ltd.

Add: Guangyang road ,Huangcheng town industrial area,Baoying County,Jiangsu Province,China

Tel:+86-514-88265689 Fax:+86-514-88261715

Declaration of Conformity

MEDICAL SWAB FOR SINGLE USE

Declaration of conformity

1、 Company name and address

Baoying County Fukang Medical Appliance Co.,Ltd.

Guangyang road,Huangcheng town industrial area,,Baoying county,Yangzhou city,Jiangsu Province. People Repulic of China

2、 Authorized EU representative name and address:

Name: Prolinx GmbH

Add:Brehmstr.56,40239 Duesseldorf ,Germany

3、 Product name: Cotton swab

4、 Classify:

Medical swab for single use

belong to class I medical devices.

We herewith declare that above product comply with EU medical devices requirements and EN ISO 13485:2016 Standard requirements. All technical documents are kept with manufacturer and attestation institution.

EU medical devices dictate:MDD/93/42/EEC

5、 Harmonize standard:

ISO13485 ISO 9001 and so on.

6、 Authentication institution:

TUV Rheinland LGA Products GmbH

7、 ISO Certificate No.

Certificate No.: SX 601504800001

Issuing date :2020-08-13

8、 General manager (signature):

