

DECLARATION OF CONFORMITY

Manufacturer: Dansu-China Health Care Co., Ltd.
No. 366 Pengjialing, Yongfeng Street Hanyang District 430050 Wuhan

European Representative: Shanghai International Holding Corp. GmbH(Europe)
Eiffestraße 80, 20537 Hamburg, Germany

Medical Device: Foam Swabstick (Conical Foam Swabsticks For PAP-test)

Classification: Class I, Non-Sterile, rule 1

Declare that this DOC is issued under our sole responsibility and refers to the following object:

Types: B9 1290

UMDNS Code: 13914

UDI-DI: (01)06947329602123

Meet the Regulation (EU) 2017/745 of the European Parliament and of the Council .

The medical device has been assigned to class I according to Annex VIII of the Regulation (EU) 2017/745.

It bears the mark



This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

STANDARDS APPLIED:

ISO13485: 2016 Medical devices-Quality management systems-Requirements for regulatory Purposes.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

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

NB Identification number: 0123
Certificate No.: Q6 059454 0030 Rev. 00
Valid from: 2021-07-01
Valid until: 2024-06-30



Wuhan
Place of issue

May 27th, 2021
Date of issue

QA, *Betty Liu*
Position, Name, Signature