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: Suture Kit

Classification- Annex IX: Class I, Sterile，rule 4

Conformity Assessment Route: Annex Ⅸ

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

Types/Model: 57000, 58000

UMDNS Code: 13892

Meet the provisions of the Council Directive 93/42/EEC which apply to them.
The medical device has been assigned to class I sterile according to Annex IX of the Directive 93/42/EEC.
It bears the mark

CE

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

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

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

NB Identification number: 0123
Certificate No.: G2S 059454 0026 Rev. 01
Expire date: 2024-05-26
Start of CE Marking: 2021-02-04

Wuhan	Jun 28th, 2023	QA, Liu Dai
Place of issue	Date of issue	Position, Name, Signature