

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: / **Jiangsu Jichun Medical Devices Co., Ltd.**
No. 98, Baiyang Bridge, Zhenglu Town, Tianning, Changzhou,
Jiangsu 213111, China
SRN: CN-MF-000019298

Registered trade name or mark: / **Disposable Insulin Syringes**

EC Authorized Representative: / **Caretechion GmbH**
Niederrheinstr. 71 40474 Düsseldorf, Germany
SRN: DE-AR-000005946

We declare under our sole responsibility that

Name of the medical device: / **Disposable Insulin Syringes**
Specifications and models: 1mL, 0.5mL, 0.3mL;
Needle specification : 0.25 (31G) 、 0.3 (30G) 、 0.33 (29G) 、
0.36 (28G) 、 0.4(27G) 、 0.45 (26G) 、 0.5 (25G)
U-100(0.3ml, 0.5ml, 1ml)
Specifications and models: 1mL, 0.5mL;
Needle specification : 0.25 (31G) 、 0.3 (30G) 、 0.33 (29G) 、
0.36 (28G) 、 0.4(27G) 、 0.45 (26G) 、 0.5 (25G)
U-40 (0.5ml, 1ml)

Product code: / **EMDN code: A020106, SINGLE-USE INSULIN SYRINGES**

Intended purpose: / **Disposable Insulin Syringes is a device that is used to inject**
insulin subcutaneously into the human body.

Basic UDI-DI: / **69586949FYDSZSQ001G8**
69586949FYDSZSQ002GA

CS reference: / **NONE**

of class: / **Rule 6, Class IIa**
According to annex VIII of Regulation (EU) 2017/745 /

Conformity assessment procedure: / **MDR Annex XI Part A**

Notified Body: / **TÜV Rheinland LGA Products GmbH**
Tillystraße 2, 90431 Nürnberg Germany

NB Identification number: / **CE0197**
Certificate No.: / **DZ 2049691-1**

Meets the provisions of the Regulation (EU) 2017/745 and other relevant Union legislation which apply to it.
The declaration is valid in connection with the "final inspection report" of the device.

Chang Zhou 2023-01-03
Ort, Datum / Place, date /
Lieu, date / Luogo, data

Wu Xuelei QM
Name und Funktion / Name and function /
Nom et fonction / Nome e funzione