

EU Certificate

Production Quality Assurance

REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A



Registration No.: DZ 2049691-1

Manufacturer: **Jiangsu Jichun Medical Devices Co., Ltd.**
No. 98 Baiyang Bridge, Zhenglu Town, Tianning,
Changzhou, 213111 Jiangsu,
P.R. China

EUDAMED Single
Registration No.: CN-MF-000019298

Products: Products of class IIa:
A010101 - HYPODERMIC NEEDLES
- Disposable Hypodermic Needles
- Disposable Safety Hypodermic Needles
- Disposable Insulin Pen Needles
A010102 - BUTTERFLY NEEDLES
- Disposable Scalp Vein Sets
A020102 - INFUSION AND IRRIGATION DISPOSABLE SYRINGES
- Disposable Syringes
- Disposable Safety Syringes
A020106 - SINGLE-USE INSULIN SYRINGES
- Disposable Insulin Syringes
A030101 - INFUSION CONTROLLERS
- Disposable Burette Infusion Sets
- Disposable Infusion Sets
- Disposable Transfusion Sets
- Disposable Transfusion Sets without Needle

Products of class I, sterile:
A030201 - EXTENSIONS
- Disposable Extension Sets
A0703 - STOPCOCKS
- 3-way Stop Cocks

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 244420156-200

Effective date: 2022-12-30

Expiry date: 2027-12-29

Issue date: 2022-12-30



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TÜV Rheinland LGA Products GmbH
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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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A020108 - SYRINGES FOR ENTERAL FEEDING
- Disposable Enteral Feeding Syringes
T020603 - MEDICAL USE FACE MASKS, TYPE I (NOT FOR HEALTHCARE PROFESSIONALS)
- Disposable Medical Face Masks
A020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR
- Disposable Medical Face Masks
A020102 - INFUSION AND IRRIGATION DISPOSABLE SYRINGES
- Disposable Syringes without Needle
- Disposable Syringes with Catheter Tips
A030101 - INFUSION CONTROLLERS
- Disposable Burette Infusion Sets without needle
- Disposable Infusion Sets without needle

For class I sterile device(s) covered in the scope, the certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

Authorised representative(s): **Caretechion GmbH**
Niederrheinstr. 71 40474 Düsseldorf, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-12-30

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