

JIANGSU ZHENGKANG MEDICAL APPARATUS CO.,LTD



江苏正康医疗器械有限公司

Address : Sanhekou,Zhenglu town,Changzhou city,Jiangsu,china

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STERILITY CERTIFICATION

Name of Product : 3-Part Disposable Syringe with Needle

SPEC AND QTY AS FOLLOWS:

Product	Quantity	Batch Number
3-Part Disposable Syringes with needle	1632000pcs/510ctns	211010
Hypodermic Needle	1340000pcs/134ctns	211010

We hereby certify all above Disposable Syringe with Needle and Infusion Set are sterilized by E.O gas in our factory, The following is the sterilization techniques parameter.

Temp for pretreatment	50℃
Humidity fro pretreatment	50±15%RH
Pretreatment	480min
Time for product transfer	<30min
Temp of sterilization tank	50±3℃
Vacuum state	-15Kap
Velocity of vacuum	4min(3.72kpa/min)
Pressure preservation	10min
Humidity for Sterilization	50±15%RH
Volume of ETO gas	12KG
EO pressure driving	26-28Kpa
Time for sterilization	360min
Vacuum degree for ventilation	-15Kap
Velocity of air exchange	3.75Kpa
Time for air exchange	18min
Time for ventilation	Trice

Place, Date of Issue:

Signature: _____

Name: Xu Tao

Position: Manager

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