

# 常州市回春医疗器材有限公司

CHANGZHOU HUICHUN MEDICAL EQUIPMENT CO.,LTD.

## Analysis certificate of Disposable Syringe

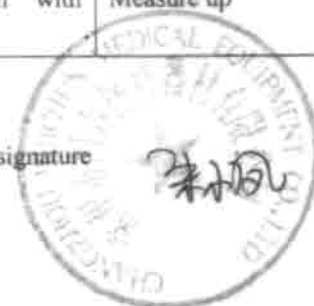
According to: ISO7886-1:1993

LOT NO.	20190315	Report NO.	20190315-4
MFG. DATE	2019/03	Spec.	10ml 21G×1 1/2"
EXP. DATE	2024/03	Test Dates	2019/03/20
QTY	352000pcs	Report Dates	2019/04/05

Inspection items	Guideline	Result
Chemical requirements	EO residua≤10ug/g	2.3ug/g
Biological requirements	There should be sterile	Measure up
	There should be no pyrogen	Measure up
Physical requirements	Taper should be conform with prescription of GB/T1962-2001	Measure up
	Sealability of syringe body: The core plug do not leak under 200kPa.The piston do not leak and fall off under-88kPa for 60+5s	Measure up
	Needle should be no burr	Measure up
	Appearance: No feathered edge, burr, plastic flow, and defect; surface is clear; coat is transparent and the base line can be seen.	Measure up
	Scale Length≥44mm	57mm
	Graduating volume line≤1ml	0.5ml
	Acceptable deviation: not more than±4% when > 1/2standard main scale	Measure up
	Piston should be no collodion silk, collodion scrapes, foreign substrate and blooming out	Measure up
	Gliding performance is good, force of push and pull is conformed with requirement	Measure up
	Volume of residual solution≤0.10ml	0.05-0.07ml
	Needle size should be conform with prescription of GB18457-2001	Size:0.8mm Length:38mm
	Needle Holder Color should be conform with prescription of YY/T0296	Measure up

Conclusion: Products measure up according to: ISO7886-1:1993.

signature



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CHANGZHOU HUICHUN MEDICAL EQUIPMENT CO.,LTD.

## STERILIZATION CERTIFICATE

Date: APR.05,2019

Product: SYRINGE/NEEDLE

Lot#: 20190315

Mfg: 2019/03

Exp: 2024/03

Specifications:

SYRINGE 2ML, 10ML,20ML

Gas Used: Ethylene Oxide Gas

Gas Composition:

Ethylene Oxide.....	99.7%
Sterilization Temperature.....	48-52°
Vacuum.....	-20±1kpa
Air Pressure.....	10-20kpa
Sterilizing Time.....	8h
Number of Vacuum.....	3 times

### Biological indicator:

The cultivated result of the biological indicator (B. Subtilis Var. niger ATCC9327, the quantity of bacteria is about  $5 \times 10^5$  to  $5 \times 10^6$ ) with the mentioned batch number is up to standard. The quantity of killing the bacteria is about  $10^6$ . So certify that the products are sterile.

### We certify that:

The above products has been sterilized with ethylene oxide in a disinfectant and found to be in conformity with sterility requirements of standard: ISO 11135-1:2007

Issue Date: APR. 05, 2019

Quality Assurance Department



## Declaration of Conformity

**Manufacturer:** Changzhou Huichun Medical Equipment Co.,Ltd.

**Address:** Sanhekou, Zhenglu Town  
213115Changzhou,Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

**European Representative:** Shanghai International Holding Corp.GmbH(Europe)

**Address:** Eiffestraße 80, 20537 Hamburg, GERMANY

**Products:** Disposable syringe, Hypodermic needle, Infusion set, Blood Collection Needle, Scalp Vein Set, Insulin Syringe, Transfusion Sets

**Classification:** (MDD Annex IX): IIa

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive and Standards (MDD/93/42/EEC). The products meet prospective uses and all supporting documentation are retained under the premise of manufacturer and the notify body.

### DIRECTIVES

#### General Applicable Directive

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD 93/42/EEC)

#### Standard:

All applicable harmonized standard (published in the Official Journal of the European Communities )

**Notify Body:** TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Munich, Germany

**Notified Body Number :** 0123

**Certificate:** G2 045876 0015 Rev.03

**Date CE Certificate is Valid from:** 2019-09-16

**Date CE mark is Valid until:** 2024-05-26

**Signature:**

**Name:**

**Position:** Managing Director