

常州市回春医疗器材有限公司

CHANGZHOU HUICHUN MEDICAL EQUIPMENT CO.,LTD.

Analysis certificate of Disposable Syringe

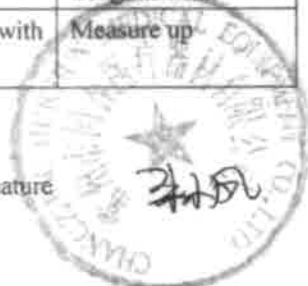
According to: ISO7886-1:1993

| | | | |
|-----------|-----------|--------------|-----------------|
| LOT NO. | 20190315 | Report NO. | 20190315-5 |
| MFG. DATE | 2019/03 | Spec. | 20ml 20G×1 1/2" |
| EXP. DATE | 2024/03 | Test Dates | 2019/03/20 |
| QTY | 400000pcs | Report Dates | 2019/04/05 |

| Inspection items | Guideline | Result |
|-------------------------|---|---------------------------|
| Chemical requirements | EO residua≤10ug/g | 2.8ug/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≥52mm | 69.1mm |
| | Graduating volume line≤2ml | 1ml |
| | 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≤0.15ml | 0.07-0.08ml |
| | Needle size should be conform with prescription of GB18457-2001 | Size:0.9mm 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



常州市回春医疗器材有限公司

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:

| | |
|--------------------------------|----------|
| Ethlene 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 5×10^5 to 5×10^6) 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): II a

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