Technology Data /Product Specification Sheet

Brand name: LELUN

Product Name: Sterile Syringe For Single Use

-Type or size: 1ml U-100 with removable needle,25G-26G,12-16mm

-Classification (MDD, Annex IX Rule X): Class IIa Rule 6

-Classification rule: The Sterile Syringe is a invasive device. The device is intended for transient use and single use. According to MDD 93/42/EEC Annex IX Rule 6, the Insulin Syringe belongs to IIa class medical devices.

1. General

Changzhou Medical Appliances General Factory Co., Ltd. was built in 1988, it is a modern factory specialized in producing the disposable medical appliance in China. The factory is only 1km to Hengshan entrance of Huning high-speed road and is about 20 miles to Changzhou airport. So the traffic is convenience.

The area of the factory is 50000m2, the area of purifying workshop is 10000m2,and fixed assets are about 5,000,000USD.Our main products are Disposable infusion sets, Disposable blood transfusion sets, Disposable Sterile syringe sets etc. Now we can manufacture more than 400,000,000 sets per year. Through ten years hard work, our hardware and software have arrived at the first-class in the same factory in China. Our trade mark "LELUN" was apprised the only "famous trade mark" in the same trade in Changzhou city. And We won the title of "High quality produce" by Jiangsu Province in 1991.In 2000; our factory passed through the ISO13485:2003 and got the certificate of CE. We also have the license of exporting by ourselves. Now our products are not only sold to all over the country, but also sold far to the other countries like Germany. Italy. Austria. France. Morocco. Turkey. Colombia. Mexico. Peru. Sri Lanka. South Africa. Yemen. Pakistan. Middle East, etc.

Our factory persists in the principle of "first quality, high credit, superior service". Sincerely welcome from all over the world to talk business and cooperate with us.

2. Structure

The syringe for single use is made of special PP and PE plastic for medical infusion、transfusion and syringe use. It is of good transparency，high machinery temperature and heat resistance，therefore is widely used in infusion、transfusion and syringe.
During usage, it will dissolve trace harmful matter in material，including heavy metal 、in volatile matter and reducing，since the amount of harmful matter is well under control, it will not cause harm to user

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3. Product Introduction

-Brief introduction: The Sterile syringe is made with medical level PP an rubber, with the scale to measure ,to inject solution into human body for clinical use. It's single use only.

-Intended Use: Intravenous injection and hypodermic injection have been basic methods of medical treatment for hundreds of years. While as the tool specifically designed for intravenous injections, the syringe for single use can be used to inject solution into human body for clinical use.

-Drawing

-Contraindication: a) Use the product by the expired date ; b) Repeat use is NOT ALLOWED

Contraindication:

a. the syringe is for single use , it should be use immediately when the packages open and be discarded after use；
b. Don't use if the package is damaged；
c. the storage place should not be under high temperature and moisture, and should be ventilated；
d. the product should be sterile with ETO, and should not be used until every inspection item is qualified; suitable environment temperature is 10~40ºC, and temperature of solution should be close to it to prevent from bubble; tenure of use of this product is five years.

Conformity Assessment Procedure: According to MDD 93/42/EEC, the company has applied for the certification of the CE marked products through the conformity assessment procedure annex V.3 and Annex VII.

Products Standard :

ISO7886-1:2017

4. Package Validation

The CE marked sterile products made in this company—Sterile Syringe using ventilating paper /PE membrane compounded bags as their package are verified according to ISO 11607-1/2:2006.

4.1 Purpose Sealing process is validated for maintenance of Seal integrity

4.2 Package equipment

The package equipment to be validated this time are B1BZ005-02, B1BZ005-03, B1BZ005-04 blister packing machine, B1BZ003-04, B1BZ003-05, B1BZ003-06, B1BZ003-07, heat sealer.

4.3 Reference Documents

-**ISO 11607：< Packaging for terminally sterilized medical devices >**

4.4 Package Validation content

Installation qualification

The Installation Qualification will utilize the package operating manual to define requirements for electrical and air pressure requirements.

Operational qualification

Operational Qualification will be completed in three phases:

- during production down time, the heat sealer will be subjected to an initial burn-in to observe the stability of the measurements of clamp closure time, temperature build and pressures.
-The second phase of operational qualification will center the process and determine initial process capability.
-The third phase of operational qualification will determine the sensitivity of the process to variations in time.

Performance qualification

Performance qualification will commence after satisfactory completion of operational qualification. Optimal settings for the package machine will be used and the package action levels for adjustment of time, temperature and pressure will be used.

4.5 Validation test items

-Accelerated aging test

-Test method: Keep the sterile products at 60°C for a given period-70 days(ASTM F 1980 that seven days at 60°C may be considered equivalent to 180 days of ageing at normal ambient conditions). Then take 6 pieces of products for sterility Test respectively, among which 6 pieces are inoculated to the anaerobic culture medium for 5 days at 30-35°C.Another 6 pieces to fungi culture medium for 7 days at 20-25°C.After incubation. observe whether or not the bacteria or fungus grows.

-Tensile seal strength test (refer to ISO-11607-1)

-Test method: Take the packages and prepare the standard—size specimen. Use the electronic rubber tensile tester to measure the tensile peel strength.

-Result: >1.1 (lbs/in)

-Impermeability and continuity of seals formed by fusion test (ISO-11607-1)

-Test method: Use ten pieces feeding tube, cut the test sample with the cutter in the middle on one side. Let 1 to 5 drops of the test solution flow down on every seal using syringe. Observe permeability of seal formed by fusion.

-Result: No dry penetration completely through the seal.

4.6 Conclusions : Qualified

5. Sterilization

The EtO sterilization procedure of Sterile Syringe produced by our company will be verified as the following processes

5.1 Purpose

Sterilization of medical products is the necessary procedure to make the medical instruments free from bacteria. To verify and monitor the effectiveness and reasonable of sterilization procedure is to ensure the products to be non-bacteria. So the EtO sterilizing procedure of Nebulizer Mask produced by this company will be verified as the following processes:

5.2 Sterilizer

The sterilizers to be validated this time are HDX 20M^3 sterilizer produced by Hangzhou Dian Da Sterilizer Factory. The 20M^3 sterilizer was produced in March 2002 and was purchased in May 2002, All parameter of the equipment can be set, and the whole processes are monitored and administered by computer.

5.3 Relative documents

EN11135 <Sterilization of Medical Device—Validation and Routine Ethylene Oxide Sterilization>

EN556 <Sterilization of Medical Device—Requirements for Medical Device To Be Labeled 'Sterile' >

EN11737 <Medical devices—Estimation of the population of micro-organism on products>

5.4 Loading and stacking pattern

According to requirements of 3.1, the packages of sterilized products are put into plastic turnover circles of 60×40×32 cm, 100 pieces in each circle, totally 100 circles, the pattern, the spaces between circles with the right and left walls of sterilizer are 50~70mm, the space between circles with the front and back walls of sterilizer are 100~150 mm, the spaces between top of sterilizer are 60～120mm, the spaces between bottom of sterilizer are 145～155mm,the space of circles is 35~40mm

5.5 Definition products

The assembling and package of Sterile Syringe is in the class 10^5 cleaning workshop. The normal environment control is according to Environment Control Way of Clean Area and Environment Control Way of Normal Producing Area, so that initiated contaminated bacteria on product is assured to be controlled in the scope of 100 cfu/piece time. test the initiated contaminated bacteria on products before sterilization see <Initiated contaminated bacteria Test Report>

5.6 Sterilization gas

100%EO produced by Shanghai Air Water Special Gas Research Institute, which has passed ISO and CE certified, whose technical target is conform to <EO---- fumigant of carbon dioxide> from China Chemical Industry Research Institute of Chemical Industry Ministry.

5.7 Bio-indicator for test

It is adopted the black varietal bacillus with lot number: 090514 as the Bio-indicator, which is produced by 3M company. Its initiated microorganism is not less than 1.0×10^6 cfu. The B.I. is packed the same way with the sterilized products.

5.8 Culture medium

Nutrition broth

6. Product Drawing and Pictures: See Bellow