Technical Documentation for

Sterile hypodermic syringes for single use(with needle)

Originator: _____

Reviewer: _____

Approver: _____

Issued Date: _____

Effective Date: _____

Manufacturer: **Jiangsu Zhengkang Medical Apparatus Co., Ltd.**

Address: **Sanhekou, Zhenglu Town, 213115 Changzhou City, Jiangsu, PEOPLE'S REPUBIC OF China.**

3. Product information

3.1. Product Description:

- **Description of the device and its intended application**

  The syringe consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both); At the distal end of the barrel is a male connector (a Luer-lock type) for the attachment of the female connector (hub) of a hypodermic needle or an administration set.

  The needle, sterile, sharp bevel-edged, hollow tubular metal device intended to be used in conjunction with syringes, to prepare and administer fluids/medications/drugs to a patient and/or to withdraw (aspirate) fluids from a patient.

  The syringe is met with ISO 7886-1 and the needle is met with ISO 7864 requirements.

  This is a single-use device.

- **Intended therapeutic and/or diagnostic indications and claims**

  It is intended for various medical applications.

3.2. Specification:

The syringe has various size according to nominal capacity, such as, 1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml and 50ml.

The detachable needle has various size according to Outside diameter, such as, 0.45mm, 0.5mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm and 1.2mm.

The nozzle have various type connector, about male/female LUER SLIP CONNECTOR, male/female LUER LOCK CONNECTOR, etc. that met with ISO 80369-7:2016

The color of needle hub has been specified for each size according to ISO 6009:2016.

Detailed size and specification was described as following:

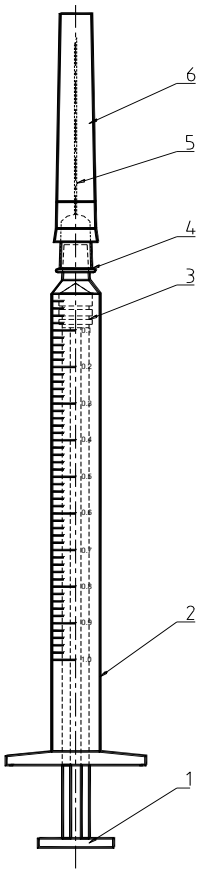
Nominal Capacity (ml)	Minimal Scale Length (mm)	Graduated capacity (ml)	Needle length(mm)	Colour

1ml	57	0.05	4.5, 5, 6	Brown, orange, deep blue.
2ml	32	0.1	4.5, 5, 6	Brown, orange, deep blue.
3ml	48	0.1	4.5, 5, 6	Brown, orange, deep blue.
5ml	41	0.2	6, 7, 8	Deep blue, black, deep green.
10ml	57.3	0.5	7, 8, 9	Black, deep green, yellow.
20ml	70	1.0	8, 9, 12	Deep green, yellow, pink.
30ml	78.9	1.0	8, 9, 12	Deep green, yellow, pink.
50ml	75	5.0	8, 9, 12	Deep green, yellow, pink.

3.3. Product drawing:

Product configuration:

1. Plunger;
2. Barrel;
3. Piston;
4. Hub;



1ml无菌注射器示意图

- **Barrel:**

The devices were sterilized by EO sterilization method which in house. EO sterilization validation should be conducted according to the DP, and detailed information was described in the ***Annex CE-ZSQ-02:*** **EO sterilization validation report.**

The shelf time of product is **3 years** after EO sterilization.

The primary material is soft blister and paper pack, re-qualification about packaging process should be conducted according to DP, and detailed information was described in the ***Annex CE-ZSQ-03:*** **Packaging validation report,** which including packaging sealing validation, aging trial and package transportation evaluation.

3.11. Labelling:

Package labeling shall include product specification, production lot number, quantity, product description, consult instruction for use, use by date, manufacturing date, do not re-use, do not use if package is damaged, caution, sterilization using EO, storage ambient, manufacturer and EU representative information, etc.

Information for labelling was drafted as per **Product labelling:** ***Annex CE-ZSQ-04*** in this Technical File.

The Organization shall ensure that only approved packaging labels shall be used and distributed together with the products. Each product unit is properly packaging to ensure its packing integrity without any damages or deterioration in nature. The production lot number and manufacturing date are identified.

The packaging and storage activities are described in the DP Preservation of Products. All packaging material shall be properly labeled according the DP Identification and Traceability.

Information on the product, such as manufacturing date, manufacturing number, and origin of manufacturer are identified on the product itself.

4. Instruction For Use (IFU)

The products are traditional devices and has simple configuration, can be used safely without instruction for use.

5. Essential requirements

The compliance of the safe and effective product towards the Essential Requirements (Annex I) of Medical Devices Directive 93/42/EEC is documented in **Essential requirements checklist**: ***Annex CE-ZSQ-05*** attached in this Technical File.

It was noted that the information generally covers the following aspects:

i. Reference number and version of any standard used;

ii. Document of procedures or reports that are used as evidence of satisfying the essential requirements

iii. Indicate whether the essential requirements are applicable or not

iv. Location where the relevant documents, procedures, work instruction or reports are being kept.

For product performance, the Organization shall ensure that the performance of the product is controlled by routine process quality monitoring and a test and inspection program.

List of applied/harmonized standards was as per **List of applied/harmonized standards:** ***Annex CE-ZSQ-06*** in this Technical File.

6. Risk analysis

The purpose of risk analysis / management is to develop a systematic approach to measure and manage risk analysis so as to produce safe and effective product by identifying the possible risks of the product becoming hazardous when defects occur during the process of product.

The risk analysis / management is applicable to the monitoring and management in the control of risks in the manufacturing and supply of the devices.

Risk management may include the addition following controls:

- Management system (to control implementation)
- Evaluation (decision about acceptability)

- Risk reduction measures, definition, implementation, verification
- Post market surveillance.

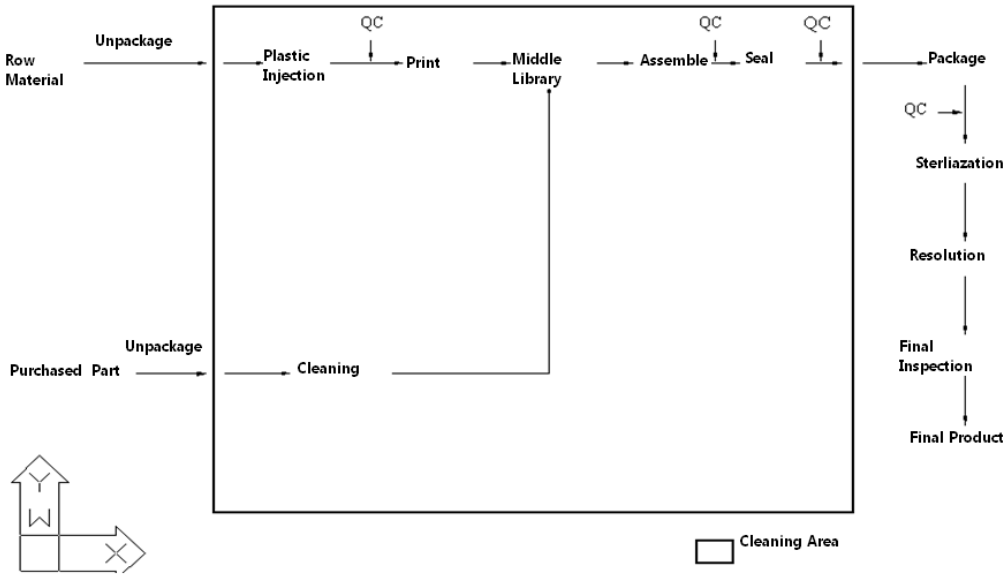
Risk Analysis had been carried on different type of risks and it is as described in the **Risk management report: *Annex CE-ZSQ-07.***

7. Manufacturing process

7.1. The manufacturing process flowchart for the device is described in this manufacturing process flowchart WI, such as, purchasing raw material (needle tube, PP, etc.), injection moulding, printing, assembling, packaging and EO sterilization, which primary packaging and EO sterilization was special process.

Mainly manufacturing process was performed at cleanroom, class 8 according to ISO 14644-1.

Primary packaging process and EO sterilization process are special process. Detailed information about flowchart as following:



The Production Work Order will be sent to the Production Officer and/or Production Technician in order to prepare and production plan for the production. The raw materials specification will also be communicate with the purchaser and the raw material and machining tooling shall be purchased from the approved suppliers according to the raw material specifications.