Technical Documentation for

Disposable Intravenous Needles

Author:ZhouLi

Approver:DingJingHua

Issued Date: 2018-6-25

Effective Date: 2018-6-28

Manufacturer: Changzhou Yuekang Medical Appliance Co., Ltd.

Address: Jiaoxi Town, Wujin County, Changzhou, Jiangsu 213116, China

Status of document change control

Revision no.	Issued date	Description of Document Change	Originator	Approved by
B/0	2018-02-28	1. All section was written with English. 2. applied standards; 3. clinical evaluation in accordance with MEDDEV 2.7/1, rev. 4.		

Table of Contents

Part A

Part A:

1. Information of Manufacturer

Changzhou Yuekang Medical Appliance Co., Ltd. (formerly Changzhou Heshou Medical Equipment Factory) is a joint-stock enterprise specializing in the production of disposable sterile medical devices. The company was founded in 1986 and now has an area of 32,000 square meters and a construction area of 25,500 square meters. Class 8 cleanroom covers an area of 7,500 square meters, currently has more than 30 million yuan in fixed assets, and currently employs 108 people. It mainly produces disposable infusion (blood) devices, disposable syringes, disposable intravenous needles, and disposables. Injecting needles and disposable medical macromolecule medical products have an annual production capacity of over 200 million sets. The product sales have been in a trend of oversupply for years. The sales covered more than 1,000 medical institutions in 28 provinces, municipalities, and autonomous regions across the country, and was praised by users. Jiangsu Province produce key medical disposable medical products.

The company has the right to self-import and export operations, through the ISO 13485 quality management system and CE certification. Our factory will provide good service and convenience to all units with excellent quality, reasonable price and timely delivery.

2. Introduction

2.1. Purpose

The purpose of this documentation is to satisfy the requirement for development, distribution and maintenance of Product Technical File in conformance with the ISO 13485, MDD 93/42/EEC and relevant regulatory bodies' requirements.

2.2. Scope

This documentation is applicable to **Disposable Intravenous Needles** manufactured and supplied by **ChangzhouYuekang Medical Appliance Co., Ltd**for distribution mainly in the European Union and relatedregional markets.

2.3. Definition

Technical File: The complete compilation of documentation demonstrating that products placed onthe market conform to the requirements specified in the Medical Device Directive (MDD) and other related regulatory requirements.

Risk Assessment: An analysis which identifies and investigates potential risks, determines if theyare hazardous and require mitigation, and identifies how such risks are to be eliminated or reduced.

Essential Requirements (ER) Checklist: A document listing the essential requirements specifiedin the MDD, and the particular standards, which demonstrate compliance to each requirement for a particular product or family. Reports or other information showing compliance with the identified standards are included.

Declaration of Conformity: A statement made by the manufacturer that a specified product meetsthe provisions of the MDD which apply, complying specifically with the standards or other normative documents defined for the product in the Essential Requirements Checklist.

Manufacturer: The person or party responsible for the design, manufacturer, and packaging of a medical device before it is placed on the market under their own name.

Substantial / Significant Change: Changes to the Quality System, Design of a Device or Technical File which affect compliance with the requirements of the relevant Regulations/Directive(s), shall be communicated to the Notified Body and the Authorized Representative.

Authorized Representative: A person or organization that resides within the European Community and serves as the official representative for the manufacturer to the Notified Body and the authorities within the member states.

2.4. Technical File Development

All products subjected to this procedure shall conform to the Essential Requirements listed in Annex I of the MDD. The information concerning this conformity is maintained in a Technical File, which is available for inspection by a competent authority in the event of an incident or the Notified Body during certification audit and surveillance audit.

The Quality Management Representative (QMR) shall be responsible for preparing and maintaining the Technical File.

The information required in Essential Requirements (Annex I of MDD 93/42/EEC) shall be included

in the Technical File.

The other information required to support the Essential Requirements and may be either included in the file or referenced by unique identification and location.

The QMR is responsible for assembling the Technical File and the GM shall approve the Technical File.

2.5. Technical File Maintenance

Changes to the Technical Files shall be prepared and processed by QMR. All changes shall be documented using Document Change Control form.

A revision page shall be maintained for each file indicating the revision date, person or department initiating the change and a brief description of the change.

Any changes in the product or process that have an impact on the contents of the Technical File shall be reflected by an update to the Status of Document Change Control in the Technical File.

Changes to the Technical File that meet the definition of substantial / significant changes shall include a notification to the Notified Body representative upon implementation.

2.6. Reporting of significant changes to QMS

The QMR shall inform the Notified Body and/or authorized body within 10 days of “significant” changes to the quality system and/or changes to the device which could affect compliance with the Essential Requirements or the intended use of the device as described in the DP - Notification to Regulatory Authority.

A notification of any significant or substantial change may include a change that could reasonably be expected to affect the safety or effectiveness of the medical devices as follows:

i. the key manufacturing process, facility or equipment;

ii. the key manufacturing, QA/QC control procedures;

iii. the key design, performance characteristics and specifications of material and device;

iv. the intended use of the device.

Significant changes that require notification to the Notified Body and/or Competent Authorities may include but are not limited to the following:

i. a change that would affect the class of the device

ii. a change in the name of the device

iii. a change in the name or address of the manufacturer

iv. a change in the product design, performance or usage

v. a change in the manufacturing process or use of critical equipment

vi. a change in the quality testing procedures (materials, process & product)

vii. a change in the name or address of the authorized representative

viii. a change in the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family.

Other changes requiring reporting may include the change of key personnel such as the QMR who is responsible for regulatory affairs and the ownership of the Quality Management System and/or the European Representative.

Upon the approval for changes from the Notified Body within the reasonable time frame, the QMR shall make the necessary amendment and/or changes to the quality system and/or changes to the device.

3. Product

3.1. Product Description

- **Indication and intended use:**

It is composed of protective sleeve, needle tube, needle handle, hose, connecting seat and protective cap.

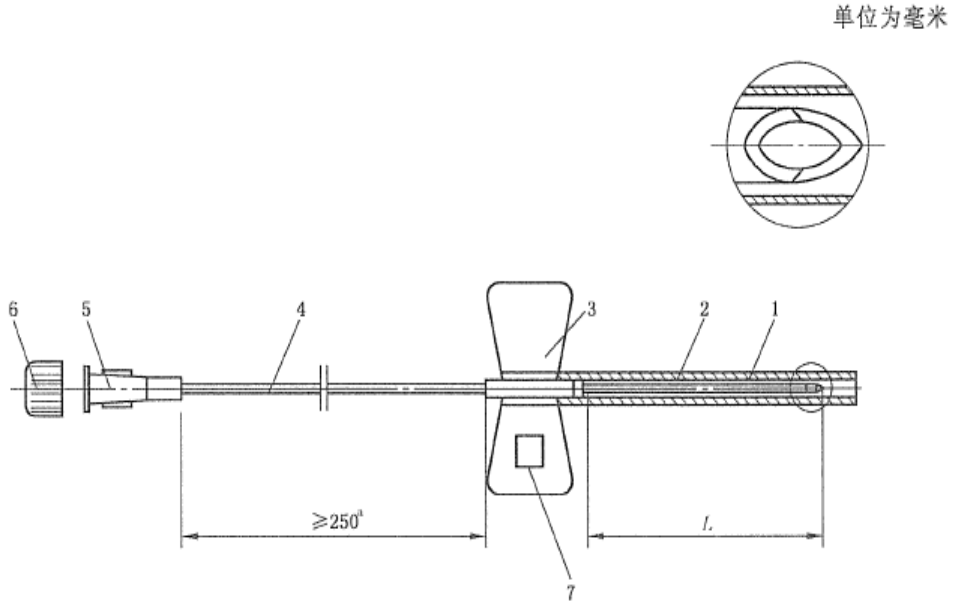
This product is only used for gravity infusion (blood).

This is a single-use device.

3.2Models:

- Needle compatible: 0.3mm(30G)、0.33mm(29G)、0.36mm(28G)、0.4mm(27G)、0.45mm(26G)、 0.5mm(25G)、 0.55mm(24G) 、0.6mm(23G)、 0.7mm(22G) 、0.8mm(21G)、0.9mm(20G) 1.1mm(19G)、1.2mm (18G)。

3.3Product drawing



1 —protective jacket 2— needle tubing 3 - needle handle 4 - tube
5 - connecting base 6 - protective jacket

3.4. Bill of material (BOM):

It was made of PVC and containing of DEHP.

The organization shall purchase incoming materials only from approved suppliers that have satisfied the selection and evaluation criteria as described in the DP. These suppliers shall be listed in the Approved Supplier List.

The material purchasing activities have been identified and documented in the DP. A detailed specification for the material used to manufacture is described in the Raw Material List. This information shall be used during material purchasing.

The incoming product quality of each batch of purchased material shall be inspected according to specification.

Inspection methods and purchased product verification activities shall be as described in the DP. The status of acceptance shall be as described in the DP- Identification and Traceability. Trained and competent personnel at site shall perform incoming material verification activities.

3.5. Performance requirements

The product performance, labelling and safety are met with GB18671-2009 requirements.

3.5.1particle pollution

In accordance with gb18671-2009 section A.1 test, the infusion needle pollution index should not exceed 90.

3.5.2connection firmness

3.5.2.1 apply 20N axial static tension at the connection of infusion needle handle and needle tube for 10s, and keep opening or loosening.
3.5.2.2 the connection between infusion needle hose and needle handle and hose and connection seat should be able to withstand 15N or 50% static axial tension (the first to be reached) for 10s without loosening or separation at each connection.

3.5.3leak

The inner cavity of infusion needle should be well sealed and should not leak when tested according to section A.2 of gb18671-2009.

3.5.4flow

In accordance with gb18671-2009 section A.3 test, at the pressure of 20kPa water output flow, should not be lower than table 1.
Note: the needle diameter given in chapter d. 1 of gb18671-2009 can be used to quickly evaluate the smoothness of the needle tube.

Table 1 infusion needle flow index

Specification /mm	0.4	0.45	0.5	0.55	0.6	0.7	0.8	0.9	1.1	1.2
Flow rate (ml/min)	2.5	2.8	3.2	3.8	5.0	11.0	21.0	36.0	48.0	

3.5.5lubricant

The syringe should be lubricated and observed with normal or corrected vision. There should be no visible accumulation of lubricant on the outer surface of the syringe.
Note 1 the lubricant is polydimethylsiloxane
Note 2: do not use more than 0.25mg of lubricant per square centimeter of needle surface.

3.5.6attachments

The conical connector of the connecting seat shall meet the requirements of GB/T1962.1 or GB/T1962.2.

3.5.7needle handle

Needle handle shall be complete, clear mark, needle handle with pinpoint inclined plane in the same direction, the slope should be no greater than 30 °.

3.5.8cases

Infusion needle protective caps should not fall off naturally and are easy to remove.

3.5.9needle

The needle tube for manufacturing infusion needle should meet the requirements of GB18457 for middle and outer diameter, surface, cleanliness, rigidity, toughness and corrosion resistance.

3.5.10 chemical properties

3.5.10.1reducing substances (easy oxides)
The difference between the volume of potassium permanganate [C (KMnO4) =0.002mol/L] consumed by the test solution and the blank solution should not exceed 2.0ml.

3.5.10.2 metal ions

The total contents of barium, chromium, copper, lead and cadmium in the test solution shall not exceed 1 g/mL when determined by atomic absorption spectrophotometer (AAS).Cadmium levels should not exceed 0.1 g/mL.

3.5.10.3 ph titration
Any standard solution required for greying the indicator shall not exceed 1ml.

3.5.10.4 evaporation residue

The total amount of evaporation residue should not exceed 2mg .

3.5.10.5 uv absorbance

The absorbance of test solution should not be greater than 0.1.

3.6. Safety

The device must comply with chemical and biocompatibility following up ISO 10993 series standards for safety.

3.7. Sterilization and Packaging

The devices were sterilized by EO sterilization in house following up ISO 11135. EO sterilization validation should be conducted according to DP, and detailed information was described in the ***Annex CE01-01: EO sterilization validation report.***

The shelf time is **3 years** after EO sterilization through by aging trial.

The primary material is coated paper and PE pouch, re-qualification about packaging process should be conducted according to DP, and detailed information (sealing validation, ageing trial and transport evaluation) was described in the ***Annex CE01-02: Packaging validation report.***

3.8. Labelling

Package labeling shall include product specification, production lot number, quantity, product description, 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 ***Annex CE01-03: Product labelling*** 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.

3.9. Instruction For Use (IFU)

The device is a conventional and simple product that can be used safely without IFU.

3.10. Product Classification

Article 9 of the MDD requires that devices be divided into Class I, IIa, IIb or III in accordance with Annex IX.

According to Annex IX, Part III, **Rule 6(2.2/1)** of the Council Directive MDD 93/42/EEC of June 1993,All surgically invasive devices intended for transient use are in Class IIa unless they are: then they are in**Class IIa**.

Device subcategory isbelongto*MD 0106: Non-active instruments.*

3.11. Reference to similar and previous generations of the device.

Similar devices of the same product groups from the manufacturer were described, and similar device from other manufacturer was also referenced into the clinical evaluation report.

3.12. European Representative

The Organization shall appoint a legal and reliable company as our Authorized European Representative.

The Organization if the Authorized Representative has a current copy of the Technical File and, if necessary, send an updated version (electronic or hard copy) within 7 days.

- The organization has been designated Caretechion GmbH as the ropean Authorized Representativethat authority and responsibility have been specified clearly following up MEDDEV 2.5/10: 2012, detailed information referred to Appendix CE01-04: EARMDD agreement.
- Information about Caretechion GmbH:
- Niederrheinstr.71,40474 Duesseldorf,Germany.
- Tel: 0049 211 3003 6618
- Fax: 0049 211 3003 6619
- Contact person: Mr. jian wang
- e-mail: info@caretechion,de
- DIMDI code: DE/0000048026.

4. 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 ***Annex CE01-05: Essential requirements checklist***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 ***Annex CE01-06: List of applied/harmonizedstandards*** in this Technical File.

5. 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 ***Annex CE01-07: Risk management report.***

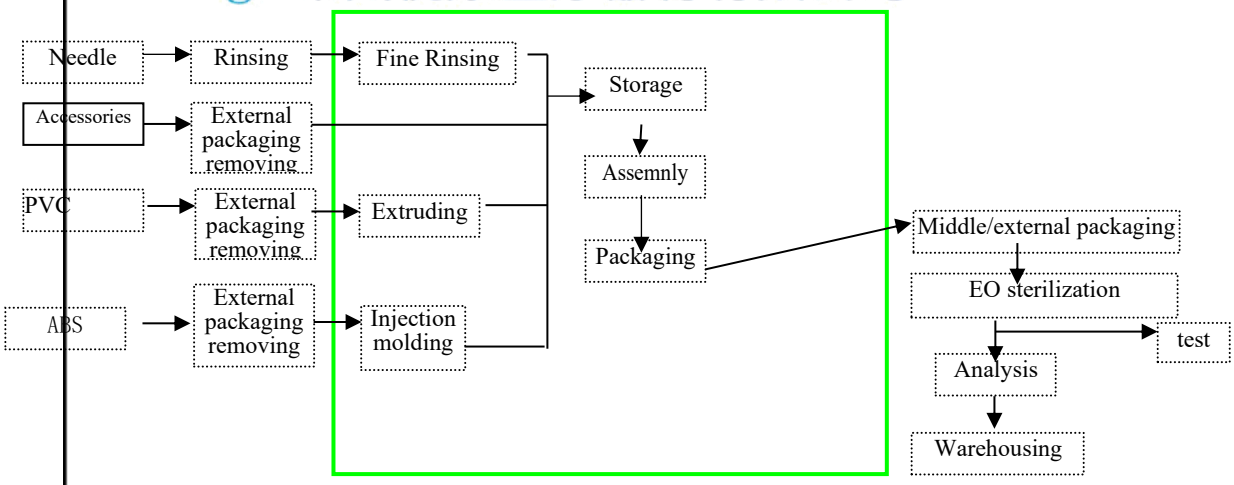
6. Manufacturing process:

6.1. The manufacturing process flowchart for the device is described in this manufacturing process flowchart, including that injection moulding, assembling, packaging and EO sterilization.

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

Primary package sealing process and EO sterilization process are special process.

Changzhou Yuekang Medical Appliance Co., Ltd.
常州悦康医疗器材有限公司



: cleanroom, class 8

* : key process

※ : special process

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.

Incoming inspection shall be carried out on every batch of incoming products as according to the DP.

All the processes mentioned above are performed according to in-house work instructions of the outsourced production service provider by trained personnel.

The competence of the personnel performing the operation shall be identified and the production processes shall be operated according to good manufacturing practices.

Steps are also taken to control product cleanliness and to avoid contamination as described in the DPs.

6.2. Storage and shipment

The assembled product shall be stored at room temperature environment. Method of product preservation is as described in the DP Preservation of Products.

The finished product shall be dispatched to the designated customers upon the issuance of shipping orders.

7. Product verification and validation

7.1. Product Testing

Prior to undertaking a clinical evaluation of the devices, pre-clinical testing is necessary and should include the following; (conformity to the standards referenced in brackets are considered to fulfill the relevant requirements of Directive 93/42/EEC).

- physical performance testing;

Testing had been carried on specific model and it is as described in the files no. ***Annex CE01-08: Physical performance testing report.***

7.2. Biocompatibility evaluation

The evaluation process was based on ISO 10993-1, 2009, annex B, *Flow chart to aid in ensuring asystematic approach to biological evaluation of medical devices.*

Initial evaluation tests for consideration were selected based on nature of body contact and contact duration, including that In Cytotoxicity, Sensitization Intracutaneous reactivity and Hemocompatibility

Because the use of these products normally entails their direct contact with patients, there is an obligation on the manufacturer to establish the safety of the products before we are marketed. Medical device safety evaluation assesses the risk of adverse health effects due to normal use and likely misuse of a device. Since adverse health effects could result from exposure to the materials from which a device is made, preclinical assessment of the toxic potential of such materials or components is needed to minimize the potential hazard to the patient.

The third party approval does is provide an independent assessment of the quality of a product, allowing potential purchasers to be confident that an impartial expert has examined the product and found it safe.

The In Cytotoxicity, Sensitization Intracutaneous reactivity and Hemocompatibilitystudy have been tested according to EN ISO 10993-5 and EN ISO 10993-10.

Testing had been carried on specific model and it is as described in the files no. ***Annex CE01-09: Biocompatibility testing report.***

From the above study, the test item is considered non-irritant to the tissues of rabbits as compared to the negative control.

7.3. Clinical evaluation

The Evaluation of clinical data is the process by which clinical data from selected sources (results of harmonized standards, physical performance testing and biocompatibility testing), provide reasonable assurance that the device materials and design are safe and appropriate for the

proposed intended use. The information provided in the below indicates that the device will not expose patients to an unreasonable or significant risk or illness or injury, and that the probable benefit to health from the use of the device outweighs the risk of injury or illness, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Published data will be assessed with respect to its possible contribution and weighting in establishing both the performance of the device in question and its safety.

Clinical evaluation files were provided under***Annex CE01-10: Clinical evaluation files.***

7.4. Update by post market surveillance activities

The manufacturer is required by the Directive to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action and to notify the Competent authorities of relevant incidents.

Post market surveillance activities should be conducted per 3 years according to the DP.

PMS files were provided under ***Annex CE01-11: Post market surveillance files***.

8. Usability

Usability engineering files were provided under ***Annex CE01-12: Usability engineering files***.

9. Declaration that no other Notified Body is used in Conformity Assessment.

The device was not certified by other Notified Body in Conformity Assessment.

10. Declaration of conformity

The QMR shall prepare a Declaration of Conformity for each device or device family. The Declaration of Conformity is described and provided in this Technical File compliance with Annex V of MDD 93/42/EEC.

Each Declaration of Conformity shall be maintained as part of the Technical File. Information for DOC was drafted as per ***Annex CE01-13: Declaration of conformity*** in this Technical File.

Part B:

Annex CE01-01: EO sterilization validation report.

Annex CE01-02: Packaging validation report.

Annex CE01-03: Product labelling.

Annex CE01-04:EAR MDD agreement.

Annex CE01-05:Essential requirements checklist.

Annex CE01-06:List of applied/harmonized standards.

Annex CE01-07: Risk management report.

Annex CE01-08: Physical performance testing report.

Annex CE01-09: Biocompatibility testing report.

Annex CE01-10: Clinical evaluation files.

Annex CE01-11:Post market surveillance files.

Annex CE01-12:Usability engineering files.

Annex CE01-13: Declaration of conformity.