DATA SHEET

Product: Hypodermic Needle :18G,20G,23G,25G,30G

Use: It is formed from a hollow needle that is usually used through a syringe and its objective is the inoculation of different types of medicines and substances in the body, as well as they are used to extract liquids from the organism as a sample, to carry out different types of analysis.

Specifications

Inspection item	Technical demands
Sterility	Sterility
Pyrogenicity	Non-Pyrogenicity
Needle Appearance	Shall be clean, no particulate and no other impurity
Needle Length	Shall be measure up
Needle Outer Diameter	Shall be measure up
Needle Seat	No burr, color shall be measure up
Protective Cap	Shall be measure up
Single Packing	Shall be measure up

Picture

Chapter 0: Administrative Information

Manufacturer:

Jiangsu Zhengkang Medical Apparatus Co.,Ltd.

San He Kou Development Zone, Zhenglu, Tianning, Changzhou 213115 Jiangsu, China

Contact:

Tel.: 0086-519-88676588

Fax: 0086-519-88679258

Website: http://www.shuangma-china.com

E-mail: shuangma8@sina.com

EU Authorizing Representative:

Lotus Global Co., Ltd.

Address: 1 Four Seasons Terrace, West Drayton, Middlesex, London, UB7 9GG, United Kingdom

Tel: +0044-20-75868010

Fax: +0044-20-79006187

E-mail: peter@lotusglobaluk.com

Notified Body:

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Deutschland

Identification no.: 0197

Chapter 1: Product Description

1.1 Overview

This technical documentation provides the documentary evidence, either by inclusion or by reference to other controlled documents and these provisions in conformity assessment procedure to the Medical Device Directive 93/42/EEC Annex V.

This technical documentation shall be applicable to the CE evaluation of conformity for Sterile Hypodermic Needles for Single Use manufactured and marketed by Jiangsu Zhengkang Medical Apparatus Co.,Ltd.

The technical documentation provides the supporting evidence demonstrating compliance with the Medical Device Directives 93/42/EEC requirements.

Jiangsu Zhengkang Medical Apparatus Co.,Ltd. has established and applies a quality management system for Manufacture and Distribution of Sterile Hypodermic Needles for Single Use, and has been certified according to EN ISO 13485 and MDD93/42/EEC by the following Notified Body:

Name: TÜV Rheinland LGA Products GmbH

Address: Tillystraße 2, 90431 Nürnberg, Deutschland

CE Identifier: 0197

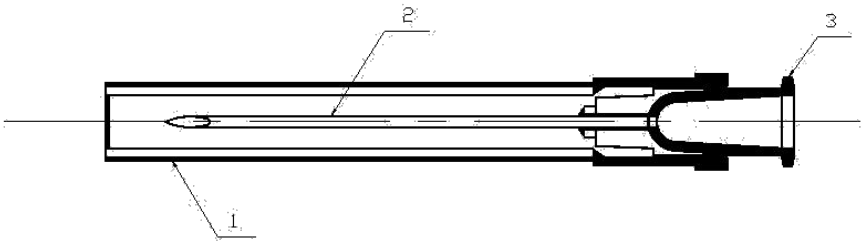
The conformity assessment by the Notified Body follows the procedure relating to the EC declaration of conformity set out in Annex V of MDD.

1.2 Intended Use

Sterile Hypodermic Needles for Single Use is a sharp, hollow instrument that connects to a syringe and is commonly used to inject liquid drugs or medications directly into the skin (under the dermis) or into a vessel, or sometimes for extracting blood.

1.3 Types and Specification

Product types: 0.3mm, 0.33mm, 0.4mm, 0.45mm, 0.5mm, 0.55mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm, 1.1mm, 1.2mm, 1.6mm for different O.D. of needle tube.
And the length of needle tube include: 9mm, 12mm, 16mm, 20mm, 25mm, 32mm, 38mm, 44mm
The sketch map for Sterile Hypodermic Needles for Single Use as following:



1.4 Cautions

Sterility is guaranteed unless the sterile pouch is damaged or seal is broken;

Check the production and expiry date printed on the sterile pouch;

Disposable device for single use;

Sterilized by ETO Sterilization;

Do NOT re-use or re-sterile;

Do not store in direct sunlight, at extreme temperature, or in high humidity;

Re-use may cause cross-infection.

1.5 Classification

Sterile Hypodermic Needles for Single Use are classified as Class IIa according to Rule 6 of MDD93/42/EEC Annex IX.

RULE 6	**VERDICT**
All surgically invasive devices intended for transient use are in Class IIa.	Class IIa

1.6 Raw Materials and Drawings

The main materials used are listed as follows:

Components	Materials
Needle Hub	PP
Needle Tube	Stainless Steel
Protective Cap	PP

The main drawing:

Components	Drawings
Finished Products	SZ/ZSZ-(0.45-1.2)-00
Hypodermic Needle	SZ/ZSZ-(0.45-1.2)-01
Needle Hub	SZ/ZSZ-(0.45-1.2)-02
Needle Tube	SZ/ZSZ-(0.45-1.2)-03
Protective Cap	SZ/ZSZ-(0.45-1.2)-04

1.7 Manufacturing Process

The mainly production flowchart as following: raw material preparation -> injection molding -> assembly -> primary packaging -> over packaging -> ETO sterilization -> warehouse

The mainly production working instructions as following:

No.	Process	WI No.
1	Production Flowchart	SM/ZY-008-01
2	Injection Molding	SM/ZY-008-10
3	Assembly	SM/ZY-008-11
4	Primary Packaging	SM/ZY-008-13
5	ETO Sterilization	SM/ZY-008-15

Manufacturing conditions: ISO Class 8 cleanroom, details refer to Working Environment Control Procedure # SM/CX-011.

1.8 Shelf Life

The product is ETO sterilized and with 5 years shelf life.

Real-time aging test report # SM/YZ-010, Rev. B/0, report date: 2017.05.02.

Chapter 2: Labeling

2.1 Overview

Labeling addresses the presentation of certain items of information that are considered by regulatory authorities to be essential for the safe and proper use of medical devices. As such, the items are required to appear with the medical device in most regulatory domains. The information can be required to appear on the medical device itself, as part of the label, or provided with the medical device.

On the labeling of the device, the symbols and information shall take consideration of the following requirements:

Annex I of Directive 93/42/EEC, esp. Section

13 EN 980: 2008

EN 1041: 2008/A1: 2013

EN ISO 15223-1: 2012

EN ISO 7864: 1996

2.2 Labeling Requirement

A labeling must include the following content:

1) Manufacturer: This symbol shall be accompanied by the name and address of the manufacturer. Indicates the medical device manufacturer, as defined in EU Directives 93/42/EEC.

2) Authorized representative in the European Community: This symbol shall be accompanied by the name and address of the authorized representative in the European Community. Indicates the Authorized representative in the European Community.

3) Date of manufacture: This symbol shall be accompanied by a date to indicate the date of manufacture. This shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. Indicates the date when the medical device was manufactured.

4) Use-by date: This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown. The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. Indicates the date after which the medical device is not to be used.

5) Batch code: This symbol shall be accompanied by the manufacturer's batch code. Indicates the manufacturer's batch code so that the batch or lot can be identified.

6) Sterilized using ethylene oxide. Indicates a medical device that has been sterilized using ethylene oxide.

7) Do not resterilize. Indicates a medical device that is not to be resterilized.

8) Do not use if package is damaged. Indicates a medical device that should not be used if the package has been damaged or opened.

9) Do not re-use. Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

10) Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

11) Keep away from sunlight. Indicates a medical device that needs protection from light sources.

12) Keep dry. Indicates a medical device that needs to be protected from moisture.

13) Temperature limit. Indicates the temperature limits to which the medical device can be safely exposed.

14) Humidity limitation. Indicates the range of humidity to which the medical device can be safely exposed.

2.3 Language Requirements

The language in label and data mostly adopts the official language of the country, it should satisfy the requirements of EEC (see the followed list), ensure the accuracy of language.

2.4 Samples of Labeling

Primary packaging labeling, refer to Attachment 1.