

Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation IFU (Disposable Insulin Pen Needle Model ST)	Compiling Dept: Technology Dept.	NO.: IFU-005-2
Page: 1 / 5	Edition/Revision: 03	Issue Date:2023.01.17

# CE Technical Documentation

## IFU of Disposable Insulin Pen Needle (ST)

According to Regulation (EU) 2017/745 Annex II and III

# Disposable Insulin Pen Needle

Basic UDI-DI: Model ST : 69340479EU12RV

Model CT: 69340479EU13RX

### Revision History

Current version	Issue date	Effective date	Previous version	Contents changed
03	2023.01.17	2023.01.17	02/00	Update Basic UDI-DI, Add European Representative.
02/00	2022.08.03	2022.08.03	01/00	Update the CE TD according to MDR

### Approval Sheet

Performed by	Name	Signature	Date
Author	Lei Shi	<i>Shi Lei</i>	2023.01.17
Reviewer	Ping Liu	<i>Liu Ping</i>	2023.01.17
Approver	Zhicheng Chen	<i>Chen Zhicheng</i>	2023.01.17

Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation IFU (Disposable Insulin Pen Needle Model ST)	Compiling Dept: Technology Dept.	NO.: IFU-005-2
Page: 2 / 5	Edition/Revision: 03	Issue Date:2023.01.17

# Instructions for Use

**Product name:** Disposable Insulin Pen Needle

**Product model:** Model ST

**Specifications:**

The outer diameter of the needle tube ranges from 30G to 33G. The needle length ranges from 3mm to 8mm.

The specification is expressed by the outer diameter and the length of the needle, such as 0.2mm(33G) x 4mm.

**Manufacturer:**

Ningbo Medsun Medical Co., Ltd.  
No.55 Jinxi Road, Zhenhai, 315221 Ningbo,  
P.R.China

**European Representative:**

Name: Shanghai International Holding Corp. GmbH (Europe)  
Address: Eiffestrasse 80, 20537 Hamburg, Germany  
Tel: 0049-40-2513175  
Fax: 0049-40-255726  
Email:shholding@hotmail.com

**Device description:**

The Disposable Insulin Pen Needle is a sterile, single-use medical device intended to be used with a pen injector device for the subcutaneous injection of insulin. Model ST is the safety type and is composed of needle hub, needle tube, protective cap, spring, slider, protective jacket, needle container and seal (dialyzing paper). The needle tube of Model ST is with thin wall. For Model ST, the needle tip is completely hidden inside the protective jacket, which is only visible when the protective jacket is pressed during injection (passive safety feature). After injection, the protective jacket will automatically spring back, and the device cannot be used again. A red warning mark will be displayed after use to indicate that the pen needle has been used.

**Intended purpose:** Disposable Insulin Pen Needle is intended to be used with a pen injector device for the subcutaneous injection of insulin.

**Intended users:** Healthcare professional and lay person.

**Target patient populations:** Paediatric patients and adults.

**Indications:** Disposable Insulin Pen Needle is intended to be used with a pen injector device for the subcutaneous injection of insulin. It is indicated for patients with type1 or type 2 diabetes who require insulin injections.

Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation IFU (Disposable Insulin Pen Needle Model ST)	Compiling Dept: Technology Dept.	NO.: IFU-005-2
Page: 3 / 5	Edition/Revision: 03	Issue Date:2023.01.17

**Contra-indications:** There are no noted contra-indications for the Disposable Insulin Pen Needle.

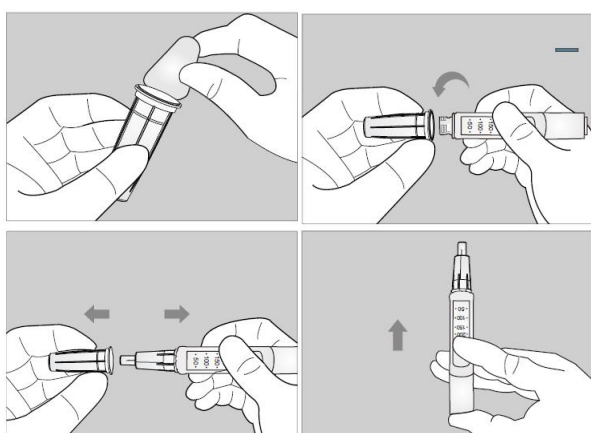
**Compatible devices:**

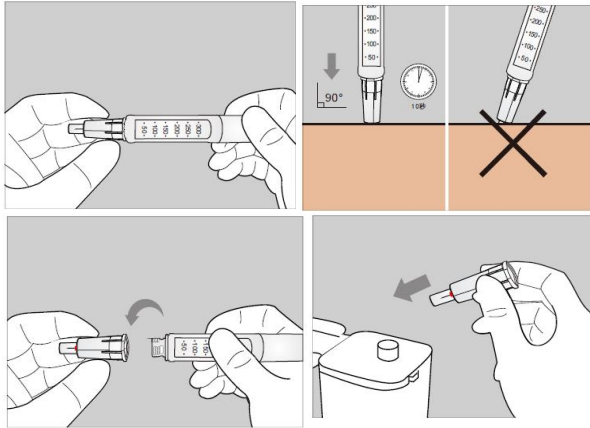
Disposable Insulin Pen Needle is intended to be used in combination with insulin pen injectors. Disposable Insulin Pen Needle is compatible with most of the available pen injectors by complying to ISO 11608-2:2012 Needle-based injection systems for medical use -- Requirements and test methods - - Part 2: Needles (Clause 4.9 and Clause 11).

The compatible insulin pen injectors include: Luxura, Luxura HD, KlikSTAR, YpsoPen, Chonghe Linbi (GensuPen 60-1), Ergo II, NovoPen4, NovoPen5, NovoPen Echo, AllStar.

**Instructions for use:**

1. Take the seal off the pen needle.
2. Attach the pen needle to the pen injector device, making sure it is on straight.
3. Remove the needle container.
4. Prime the pen injector according to the pen injector device instructions for use. Check the flow. A drop of liquid should appear at the needle tip. Please note that a priming droplet may remain and be left on the skin after injection.
5. Select the dose prescribed by your health care professional.
6. Push the needle protective jacket against taut skin (at a 90° angle) following the injection technique demonstrated by your health care professional. The protective jacket will retract and allow the needle to penetrate the skin. To ensure a firmer surface at the injection site, you may also pinch up the skin to create a skinfold.
7. Do not change the direction of the needle when it is still in the skin to avoid bending.
8. After the injection, hold needle in place 10 seconds before removing the needle from the skin.
9. On withdrawal from the skin, the protective jacket will lock, the red indicator will confirm that the safety mechanism has been activated. The pen needle cannot be used again.
10. Discard the needle into a sharp's container.





### Warnings and precautions:

- Please read the Instructions for Use carefully before using the product.
- The product is for single use only. Do not reuse. Reusing the pen needle could cause pain, bleeding, bruising, scarring, increased risk of infection, lipohypertrophy, increased risk of the needle breaking off in the skin.
- Pen needles are provided sterile. Do not resterilise.
- Do not use the product if the seal is damaged or unintentionally opened before use.
- If the product is damaged or contaminated, do not use the product.
- Do not use the product if the shelf life has expired.
- Consult healthcare professionals for the appropriate model and specification, injection technique and site for you.
- Handle the product carefully to avoid needlestick injuries.
- Dispose the pen needles immediately after use into an approved sharps disposal container in accordance with facility guidelines and local regulations.

### Residual risks and undesirable side-effects:

Lipohypertrophy could happen in response to the adipogenic actions of insulin at a site of multiple injections. Injection site rotation is necessary to avoid lipohypertrophy. Please consult healthcare professionals for the appropriate injection technique and site for you.

In rare cases, hyperglycemia or hypoglycemia could be caused by inaccurate dosing due to device problems.

**Sterilisation method:** EO Sterilization

**Shelf life:** 5 years



**Storage:** The Disposable Insulin Pen Needle shall be stored in dry and clean place with a relative humidity of no more than 80%, good ventilation. Avoid exposure to strong light. Recommend to store in room temperature.



**Symbols:**



Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation IFU (Disposable Insulin Pen Needle Model ST)	Compiling Dept: Technology Dept.	NO.: IFU-005-2
Page: 5 / 5	Edition/Revision: 03	Issue Date:2023.01.17




 Manufacturer  Authorized representative in the European Community

 Date of manufacture  Use-by date  Batch code

 Do not use if package is damaged  Do not re-use

 Sterilized Using Ethylene Oxide  Do not re-sterilize

 Consult instructions for use  Medical device

 Caution  Keep dry  Keep away from sunlight

**Incident reporting:**

The user and/or patient shall report any serious incident that has occurred in relation to the device to Ningbo Medsun Medical Co., Ltd and the competent authority of the EU Member State in which the user and/or patient is established.

Date of issue: 2023.01.17

Revision: 03