

Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation IFU (Disposable Insulin Pen Needle Model CT)	Compiling Dept: Technology Dept.	NO.: IFU-005-1
Page: 1 / 4	Edition/Revision: 03	Issue Date:2023.01.17

CE Technical Documentation

IFU of Disposable Insulin Pen Needle (CT)

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 CT)	Compiling Dept: Technology Dept.	NO.: IFU-005-1
Page: 2 / 4	Edition/Revision: 03	Issue Date:2023.01.17

Instructions for Use

Product name: Disposable Insulin Pen Needle

Product model: Model CT

Specifications:

The outer diameter of the needle tube ranges from 30G to 33G. The needle length ranges from 3mm to 12mm.

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 CT is composed of needle hub, needle tube, needle shield, needle container and seal (dialyzing paper). The needle tube of Model CT is with thin wall.

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.

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

Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation IFU (Disposable Insulin Pen Needle Model CT)	Compiling Dept: Technology Dept.	NO.: IFU-005-1
Page: 3 / 4	Edition/Revision: 03	Issue Date:2023.01.17

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. Remove the seal from the pen needle.
2. Push the pen needle straight on to the pen injector device and twist until it is tight.
3. Remove the needle container and the needle shield carefully to avoid the bending of the needle. Discard the needle shield.
4. Prime the pen injector as the pen's instructions to prevent incorrect dosage caused by air in the cartridge or a clogged needle.
5. Set the insulin dose required as the pen's instructions.
6. Inject insulin. Consult your healthcare professional in advance about the appropriate injection technique for you.
7. Do not change the direction of the pen needle while it remains in your body, as this can result in bending or breaking of the needle.
8. Do not withdraw the needle immediately after injection, wait for more than 10 seconds before removing it.
9. After use, discard the pen needle into a sharp collection box.

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:

The product is single use only. 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.

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.

Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation IFU (Disposable Insulin Pen Needle Model CT)	Compiling Dept: Technology Dept.	NO.: IFU-005-1
Page: 4 / 4	Edition/Revision: 03	Issue Date:2023.01.17

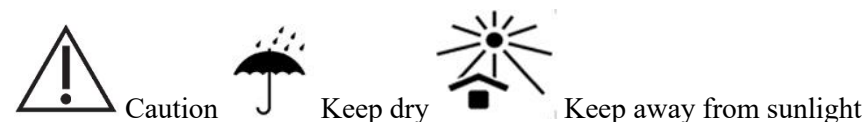
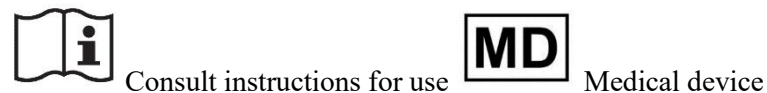
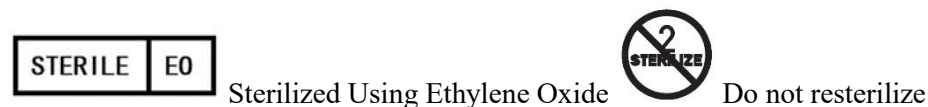
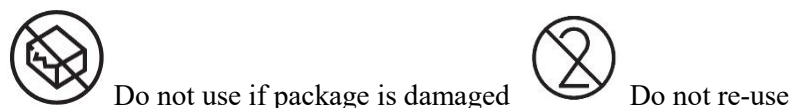
In rare cases, hyperglycemia or hypoglycemia could be caused by inaccurate dosing due to device problems.

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:



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