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| Zhejiang Longde Pharmaceutical Co.,Ltd. | CE Technical Document   |
| <b>Instruction For Use</b>              | Document No.: LD-IFU-01 |
|                                         | Control Status: Rev.1   |

## Instruction For Use

### Sterile Hypodermic Syringes for Single Use

Please read the instruction book carefully before using



**Date of issue and edition:** 2025-03-15 Rev.2

**[Product name]:** Sterile Hypodermic Syringes for Single Use

**[Model and Specification]**

| Product specification              |          |                            |                                                                                                             |
|------------------------------------|----------|----------------------------|-------------------------------------------------------------------------------------------------------------|
| Type                               | Capacity | Luer conical               | Needle specification                                                                                        |
| Three-piece type<br>Two-piece type | 1ml      | luer lock, or luer<br>slip | 12G,13G,14G,15G,<br>16G,17G,18G,19G,20G,21G,<br>22G,23G,24G,25G,26G,27G,<br>28G,29G,30G,31G,32G,33G,<br>34G |
|                                    | 2ml      |                            |                                                                                                             |
|                                    | 2.5ml    |                            |                                                                                                             |
|                                    | 3ml      |                            |                                                                                                             |
|                                    | 5ml      |                            |                                                                                                             |
|                                    | 10ml     |                            |                                                                                                             |
|                                    | 20ml     |                            |                                                                                                             |
|                                    | 30ml     |                            |                                                                                                             |
|                                    | 50ml     |                            |                                                                                                             |
|                                    | 60ml     |                            |                                                                                                             |

**[Intended use]:**

This device is intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

**[Intended patient population]:**

Patients who require injections or withdrawals of medicines and other fluids.

**[Intended users]:**

Medical professionals.

**[Indications]:**

None.

**[limitation]:**

Use is restricted to trained physicians or caregivers.

**[Structural composition]:**

The product is composed of outer barrel and plunger (or with piston) and needle.

**[Contra-indication]:**

No contraindications.

**[Caution]:**

1. Non-toxic, pyrogen-free
2. Destroy if the package is not intact
3. Destroy after single use, harmless treatment shall be carried out in accordance with the regulations on the disposal of medical waste.
4. Not to be used with paraldehyde

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**[Warning]:**

No warning.

**[The main performance characteristics of the device]:**

1. Dead space: Shall comply with the terms of ISO 7886-1

2. Air tightness (negative pressure):

When tested in accordance with ISO 7886, there shall be no leakage of air past the piston or seal (s), and there shall be no fall in the manometer reading.

3. Water tightness (positive pressure):

When tested in accordance with ISO 7886, there shall be no leakage of water past the piston or seal (s).

4. Fit of plunger stopper/plunger in barrel:

When the syringe is filled with water to the nominal capacity and held vertically with first one end and then the other end uppermost, the piston shall not move by reason of its own mass and the water contained

5. Please refer to ISO 7886-1:2017 for the rest of the performance description.

**[Application method]:**

1. Taking care not to contaminate the product during it's being taken from package

2. Assembling the syringe with needle, take off the needle cap and protective end cap;

3. Sucking a given amount of liquid, and expelling air, then injecting;

4. This product is limited to single use and should be destroyed after use.

5. Do not use if the package is damaged or open before use. The product shall be used within the stipulated valid period.

**[Storage and transportation]:**

**Storage:** The sterilized syringe should be stored in a non-corrosive gas, well-ventilated and clean room, and the syringe should be fully protected.

**Transportation :** The outer packaging should be able to ensure that it will not be damaged under normal transportation conditions.

**[Shelf life]:**

See the label for details.



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SRN: BE-AR-000000106



**Company name:**

**Address:**

**SRN:**

**[Label identification]:**

|  |                                                                         |  |                                                                     |
|--|-------------------------------------------------------------------------|--|---------------------------------------------------------------------|
|  | Manufacturer                                                            |  | Authorized representative in the European Community/ European Union |
|  | Date of manufacture                                                     |  | Use-by date                                                         |
|  | Batch code                                                              |  | Do not re-use                                                       |
|  | Catalogue number                                                        |  | Sterilized using ethylene oxide                                     |
|  | Do not use if package is damaged and consult instructions for use       |  | Non-pyrogenic                                                       |
|  | Single sterile barrier system                                           |  | Keep away from sunlight                                             |
|  | Keep dry                                                                |  | Caution                                                             |
|  | Consult instructions for use or consult electronic instructions for use |  | CE marking                                                          |
|  | Medical device                                                          |  | Indicates the entity importing the medical device into the locale   |

**Product Tolerance on any graduated capacity and scale interval**

| Nominal capacity<br>of syringe<br>V<br>mL | Tolerance on any graduated capacity  |                                                   | Maximum scale<br>interval<br>ml |
|-------------------------------------------|--------------------------------------|---------------------------------------------------|---------------------------------|
|                                           | Less than half nominal<br>capacity   | Equal to or greater than half<br>nominal capacity |                                 |
| V<2                                       | ±(1.5% of V + 2% of expelled volume) | ±5% of expelled volume                            | 0.05                            |
| 2≤V<5                                     | ±(1.5% of V + 2% of expelled volume) | ±5% of expelled volume                            | 0.2                             |

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|------------------|-------------------------------------------------------------|--------------------------------------|-----|
| $5 \leq V < 10$  | $\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$ | $\pm 4\% \text{ of expelled volume}$ | 0.5 |
| $10 \leq V < 20$ | $\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$ | $\pm 4\% \text{ of expelled volume}$ | 1.0 |
| $20 \leq V < 30$ | $\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$ | $\pm 4\% \text{ of expelled volume}$ | 2.0 |
| $30 \leq V < 50$ | $\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$ | $\pm 4\% \text{ of expelled volume}$ | 2.0 |
| $V \geq 50$      | $\pm(1.5\% \text{ of } V + 1\% \text{ of expelled volume})$ | $\pm 4\% \text{ of expelled volume}$ | 5.0 |

|                                         |                           |
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| <b>Label</b>                            | Document No.: LD-Label-01 |
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Sterile Hypodermic Syringes for Single Use

Lot:

2 mL

Qty:1

Zhejiang Longde Pharmaceutical Co.,Ltd.

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Destroy after use

Non-Pyrogenic

Destroy if the package is not intact

Not made with natural rubber latex

