

## Technical Data Sheet

### 1. Product name

Insulin Syringes.

### 2. General information

#### 2.1. Legal manufacturer

|                |                                                                                                       |
|----------------|-------------------------------------------------------------------------------------------------------|
| <b>Name</b>    | Promisemed Hangzhou Meditech Co., Ltd.                                                                |
| <b>Address</b> | No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China. |

#### 2.2. Design and manufacturing site

|                            |                                                                                                       |
|----------------------------|-------------------------------------------------------------------------------------------------------|
| <b>Name</b>                | Promisemed Hangzhou Meditech Co., Ltd.                                                                |
| <b>Address</b>             | No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China. |
| <b>QMS certificate no.</b> | SX 2091024-1                                                                                          |
| <b>CE Certificate no.</b>  | HZ 2091024-1                                                                                          |

#### 2.3. General

Intended use: It is intended for subcutaneous injection of insulin in the treatment of diabetes.

#### Type 7

**U-40**



**0.3ml**

**0.5ml**

**1.0ml**

**U-100**



**0.3ml**

**0.5ml**

**1.0ml**

## Type 8

### U-40



0.3ml

0.5ml

1.0ml

### U-100



0.3ml

0.5ml

1.0ml

It is a sterile device consisting of a calibrated barrel with plunger, is intended to be used to administer an injection of insulin to a patient subcutaneously. A non-retractable integrated needle is included. The syringe is made of plastic and silicone materials and allowing smooth plunger movement.

This is a single-use device and delivered sterile. Sterilization process is validated according to EN ISO 11135. Sterilization process undergoes routine control.

## 2.4. Gauge and diameter information

| Type              | Unit scale     | Capacity                   | Gauge | Outer Diameter (mm) |       | Inner Diameter (mm) |
|-------------------|----------------|----------------------------|-------|---------------------|-------|---------------------|
|                   |                |                            |       | Min.                | Max.  |                     |
| Type 7,<br>Type 8 | U-40,<br>U-100 | 0.3ml,<br>0.5ml,<br>1.0ml. | 32G   | 0.229               | 0.241 | $\geq 0.089$        |
|                   |                |                            | 31G   | 0.254               | 0.267 | $\geq 0.114$        |
|                   |                |                            | 30G   | 0.298               | 0.320 | $\geq 0.133$        |
|                   |                |                            | 29G   | 0.324               | 0.351 | $\geq 0.133$        |
|                   |                |                            | 28G   | 0.349               | 0.370 | $\geq 0.133$        |

## 2.5. Specification code

| Type   | Unit scale | Capacity | Specification code                                                                                                                                                                              |
|--------|------------|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Type 7 | U-40       | 0.3ml    | ISY-7032806-40, ISY-7032808-40, ISY-7032812-40, ISY-7032906-40, ISY-7032908-40, ISY-7032912-40, ISY-7033006-40, ISY-7033008-40, ISY-7033012-40, ISY-7033106-40, ISY-7033108-40, ISY-7033112-40, |

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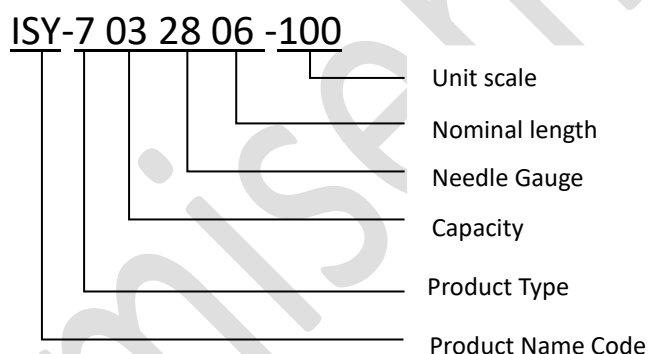
|        |       |       |                                                                                                                                                                                                                                                                |
|--------|-------|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Type 8 |       |       | ISY-7033206-40, ISY-7033208-40, ISY-7033212-40.                                                                                                                                                                                                                |
|        |       | 0.5ml | ISY-7052806-40, ISY-7052808-40, ISY-7052812-40, ISY-7052906-40, ISY-7052908-40, ISY-7052912-40, ISY-7053006-40, ISY-7053008-40, ISY-7053012-40, ISY-7053106-40, ISY-7053108-40, ISY-7053112-40, ISY-7053206-40, ISY-7053208-40, ISY-7053212-40.                |
|        |       | 1.0ml | ISY-7102806-40, ISY-7102808-40, ISY-7102812-40, ISY-7102906-40, ISY-7102908-40, ISY-7102912-40, ISY-7103006-40, ISY-7103008-40, ISY-7103012-40, ISY-7103106-40, ISY-7103108-40, ISY-7103112-40, ISY-7103206-40, ISY-7103208-40, ISY-7103212-40.                |
|        | U-100 | 0.3ml | ISY-7032806-100, ISY-7032808-100, ISY-7032812-100, ISY-7032906-100, ISY-7032908-100, ISY-7032912-100, ISY-7033006-100, ISY-7033008-100, ISY-7033012-100, ISY-7033106-100, ISY-7033108-100, ISY-7033112-100, ISY-7033206-100, ISY-7033208-100, ISY-7033212-100. |
|        |       | 0.5ml | ISY-7052806-100, ISY-7052808-100, ISY-7052812-100, ISY-7052906-100, ISY-7052908-100, ISY-7052912-100, ISY-7053006-100, ISY-7053008-100, ISY-7053012-100, ISY-7053106-100, ISY-7053108-100, ISY-7053112-100, ISY-7053206-100, ISY-7053208-100, ISY-7053212-100. |
|        |       | 1.0ml | ISY-7102806-100, ISY-7102808-100, ISY-7102812-100, ISY-7102906-100, ISY-7102908-100, ISY-7102912-100, ISY-7103006-100, ISY-7103008-100, ISY-7103012-100, ISY-7103106-100, ISY-7103108-100, ISY-7103112-100, ISY-7103206-100, ISY-7103208-100, ISY-7103212-100. |
|        | U-40  | 0.3ml | ISY-8032806-40, ISY-8032808-40, ISY-8032812-40, ISY-8032906-40, ISY-8032908-40, ISY-8032912-40, ISY-8033006-40, ISY-8033008-40, ISY-8033012-40, ISY-8033106-40, ISY-8033108-40, ISY-8033112-40, ISY-8033206-40, ISY-8033208-40, ISY-8033212-40.                |
|        |       | 0.5ml | ISY-8052806-40, ISY-8052808-40, ISY-8052812-40, ISY-8052906-40, ISY-8052908-40, ISY-8052912-40, ISY-8053006-40, ISY-8053008-40, ISY-8053012-40, ISY-8053106-40, ISY-8053108-40, ISY-8053112-40, ISY-8053206-40, ISY-8053208-40, ISY-8053212-40.                |
|        |       | 1.0ml | ISY-8102806-40, ISY-8102808-40, ISY-8102812-40, ISY-8102906-40, ISY-8102908-40, ISY-8102912-40, ISY-8103006-40, ISY-8103008-40, ISY-8103012-40, ISY-8103106-40, ISY-8103108-40, ISY-8103112-40, ISY-8103206-40, ISY-8103208-40, ISY-8103212-40.                |

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|       |       |                                                                                                                                                                                                                                                                            |
|-------|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| U-100 | 0.3ml | ISY-8032806-100, ISY-8032808-100, ISY-8032812-100,<br>ISY-8032906-100, ISY-8032908-100, ISY-8032912-100,<br>ISY-8033006-100, ISY-8033008-100, ISY-8033012-100,<br>ISY-8033106-100, ISY-8033108-100, ISY-8033112-100,<br>ISY-8033206-100, ISY-8033208-100, ISY-8033212-100. |
|       | 0.5ml | ISY-8052806-100, ISY-8052808-100, ISY-8052812-100,<br>ISY-8052906-100, ISY-8052908-100, ISY-8052912-100,<br>ISY-8053006-100, ISY-8053008-100, ISY-8053012-100,<br>ISY-8053106-100, ISY-8053108-100, ISY-8053112-100,<br>ISY-8053206-100, ISY-8053208-100, ISY-8053212-100. |
|       | 1.0ml | ISY-8102806-100, ISY-8102808-100, ISY-8102812-100,<br>ISY-8102906-100, ISY-8102908-100, ISY-8102912-100,<br>ISY-8103006-100, ISY-8103008-100, ISY-8103012-100,<br>ISY-8103106-100, ISY-8103108-100, ISY-8103112-100,<br>ISY-8103206-100, ISY-8103208-100, ISY-8103212-100. |

Code expression:



### 2.6. Classification

According to Annex VIII, Chapter III, **Rule 6(5.2.1)** of Regulation (EU) 2017/745, the needle tube was subcutaneous injection for insulin, transient use (<1 minute), then they are in **Class IIa**.

### 2.7. Basic UDI-DI

| Product name     | Basic UDI-DI   |
|------------------|----------------|
| Insulin Syringes | 697122740ISYQY |

### 2.8. Material

| Component | Material                                                  |
|-----------|-----------------------------------------------------------|
| Barrel    | Polypropylene (PP)                                        |
| Plunger   | Polypropylene (PP)/ Acrylonitrile butadiene styrene (ABS) |

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|                    |                                       |
|--------------------|---------------------------------------|
| Needle cap         | Polyethylene (PE)/ Polypropylene (PP) |
| Protective end cap | Polyethylene (PE)                     |
| Piston             | Polyisoprene rubber                   |
| Needle tube        | X5CrNi18-10                           |
| Lubricant          | Silicon oil                           |
| Needle tip         | 3 bevels                              |

### 2.9. Material of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

| Material                            | Comment                                                          |
|-------------------------------------|------------------------------------------------------------------|
| Phthalates                          | No phthalates intentionally added.                               |
| DEHP                                | No DEHP intentionally added.                                     |
| Medicinal Substance                 | The products do not contain medicinal substance.                 |
| Carcinogenic substance              | The products do not contain carcinogenic substance.              |
| Toxic chemical                      | The products do not contain toxic chemical.                      |
| Latex                               | The products do not contain natural latex.                       |
| Substances of animal origin BSE/TSE | The products do not contain substances of animal origin BSE/TSE. |
| Polyvinyl chloride (PVC)            | The products do not contain polyvinyl chloride.                  |

### 2.10. Biocompatibility

**Promisemed** medical products comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

### 2.11. Sterilization

Ethylene Oxide Sterilization following EN ISO 11135-1. EO residues are within applicable regulations.

### 2.12. Shelf life

The shelf-life is **5 years**.

## 2.13. Storage requirements

Store the product on a cool and dry place, keep away from sunlight, heat and humidity.

## 2.14. Standards

| Designation number and date | Title of standard ( <i>Harmonised Standards</i> )                                                                                                                                 |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| EN ISO 10993-1:2020         | <i>Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process</i>                                                                 |
| EN ISO 10993-4:2017         | <i>Biological evaluation of medical devices —Part 4: Selection of tests for interactions with blood</i>                                                                           |
| EN ISO 10993-5:2009         | <i>Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity</i>                                                                                         |
| EN ISO 10993-10: 2013       | <i>Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization</i>                                                                            |
| EN ISO 10993-11:2018        | <i>Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity</i>                                                                                           |
| EN ISO 10993-12: 2012       | <i>Biological evaluation of medical devices - Part 12: Sample preparation and reference materials</i>                                                                             |
| EN ISO 11607-1:2020         | <i>Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems</i>                                    |
| EN ISO 11607-2:2020         | <i>Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes</i>                                          |
| EN ISO 11737-1:2018         | <i>Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products</i>                                           |
| EN ISO 11737-2:2020         | <i>Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process</i> |
| EN ISO 11135:2014           | <i>Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices</i>   |
| EN ISO 11138-1:2017         | <i>Sterilization of health care products - Biological indicators - Part 1: General requirements</i>                                                                               |
| EN ISO 11138-2:2017         | <i>Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes</i>                                   |
| EN ISO 14644-1:2015         | <i>Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration</i>                                                    |
| EN ISO 14644-2:2015         | <i>Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration</i>   |

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EN ISO 14644-8:2013 *Cleanrooms and associated controlled environments — Part 8: Classification of airborne molecular contamination*

EN ISO 14698-2:2003/Cor 1:2004 *Cleanrooms and associated controlled environments- Bio contamination control — Part 2: Evaluation and interpretation of bio contamination data*

EN ISO 14971:2019 *Medical devices - Application of risk management to medical devices*

BS ISO 15510:2014 *Stainless steels — Chemical composition*

EN ISO 15223-1:2021 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

EN ISO 20417:2021 *Medical devices - Information to be supplied by the manufacturer*

EN 556-1:2001/ AC:2006 *Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices*

EN 62366-1:2015/A1:2020 *Medical devices - Application of usability engineering to medical devices*

EN ISO 780:2015 *Packaging — Distribution packaging— Graphical symbols for handling and storage of packages*

EN ISO 7864:2016 *Sterile hypodermic needles for single use — Requirements and test methods*

EN ISO 8537:2016 *Sterile single-use syringes, with or without needle, for insulin*

EN ISO 9626:2016 *Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods*

### Standard designation number and date

### Title of standard (Non Harmonised Standards)

ISO 14698-1:2003 *Cleanrooms and associated controlled environments – Bio contamination control- Part 1: General principles and methods*

ISO 2859-1:1999 *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ASTMD 4169:2016 *Standard Practice for Performance Testing of Shipping Containers and Systems*

ASTM F1980-2016 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*

MEDDEV 2.7/1, rev. 4 *CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC*

### 3. Package

#### 3.1. Package materials

## Technical Data Sheet



| Content                | Description                                                                                    |
|------------------------|------------------------------------------------------------------------------------------------|
| Unit package           | Type 7: Sterile barrier system is consisting of <u>Blister film</u> + <u>Dialyzing paper</u> . |
|                        | Type 8 : PE bags                                                                               |
| User package           | Paper board                                                                                    |
| Transportation package | Double corrugated carton                                                                       |

### 3.2. Packaging specifications

| Product Name     | Box     | Carton   |
|------------------|---------|----------|
| Insulin Syringes | 100 pcs | 20 boxes |

**Note :** The quantity of package can be provided following up customer requirements.

**Note:**

***This document is approved electronically.***

***This document can be changed without further notification.***