Technical Data Sheet

1. Product name

Mechanical Safety Insulin Syringes.

2. General Information

2.1. Legal Manufacturer

Name	Promisemed Hangzhou Meditech Co., Ltd.
Address	No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.

2.2. Design and manufacturing site

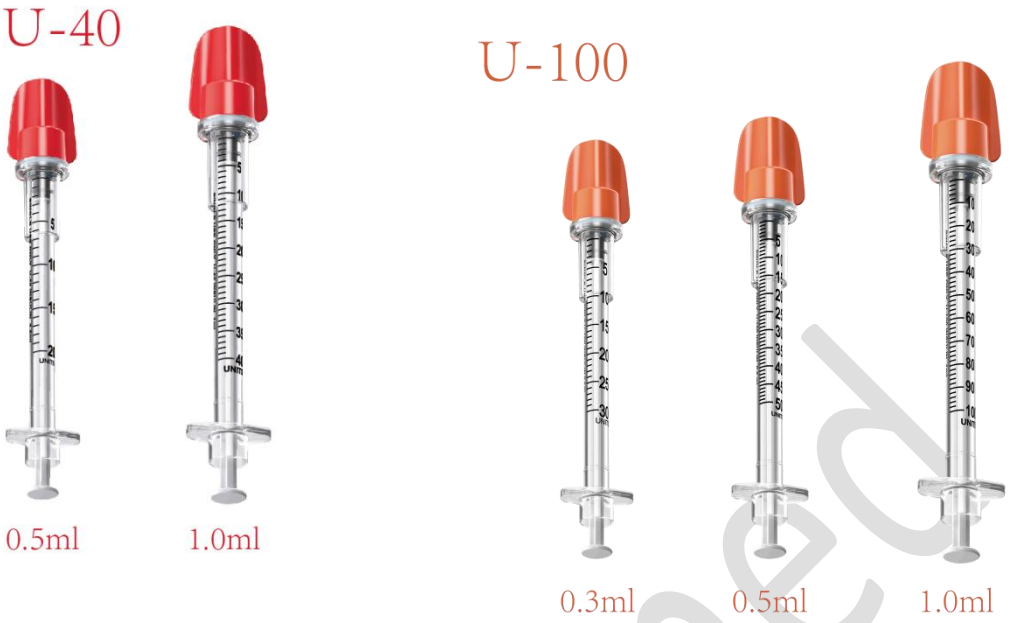
Name	Promisemed Hangzhou Meditech Co., Ltd.
Address	No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.
QMS certificate no.	SX 2091024-1
CE Certificate no.	HZ 2091024-1

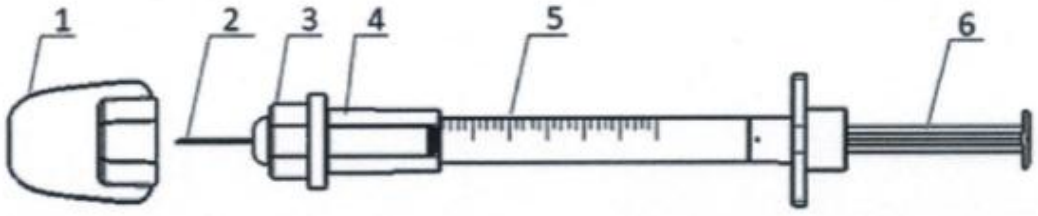
2.3. Product classification

USA	II K210712
EU	IIa, CE0197

2.4. General

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





1.Needle cap; 2.Needle tube; 3.Upper cover;
4.Sliding sleeve; 5.Protective shield; 6.Plunger

It is a sterile device consisting of a needle cap, a needle tube, a upper cover, a sliding sleeve, a Protective shield and a plunger. It is intended to be used to inject insulin to subcutaneouse tissue.

It includes an attached needle with a safety mechanism, such as, protective shield temporarily covers needle; after injection, the shield is permanently locked in place by pulling forward and twisting, providing protection against needle sticks and rendering the device unusable.

It can be used by health care personnel.

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

2.5. Gauge and Diameter information

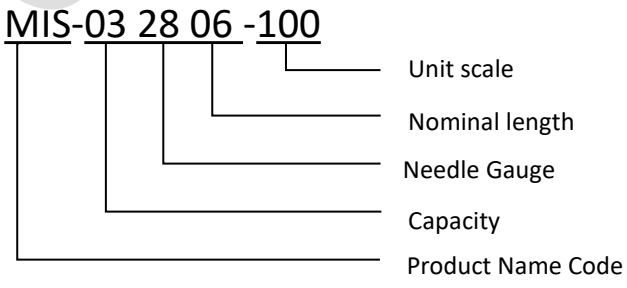
Unit scale	Capacity	Outer Diameter (mm)		Inner Diameter (mm)	
U-40	0.5ml 1.0ml	Min.	Max.	Regular wall	Thin wall
		0.229	0.241	0.089	0.105

		0.254	0.267	0.114	0.125
U-100	0.3ml	0.298	0.320	0.133	0.165
	0.5ml	0.324	0.351	0.133	0.190
	1.0ml	0.349	0.370	0.133	0.190

2.6. Specification code

Unit scale	Specification code
U-100	MIS-032806-100, MIS-032808-100, MIS-032812-100, MIS-032906-100, MIS-032908-100, MIS-032912-100, MIS-033006-100, MIS-033008-100, MIS-033012-100, MIS-033106-100, MIS-033108-100, MIS-033112-100, MIS-033206-100, MIS-033208-100, MIS-033212-100.
	MIS-052806-100, MIS-052808-100, MIS-052812-100, MIS-052906-100, MIS-052908-100, MIS-052912-100, MIS-053006-100, MIS-053008-100, MIS-053012-100, MIS-053106-100, MIS-053108-100, MIS-053112-100, MIS-053206-100, MIS-053208-100, MIS-053212-100.
	MIS-102806-100, MIS-102808-100, MIS-102812-100, MIS-102906-100, MIS-102908-100, MIS-102912-100, MIS-103006-100, MIS-103008-100, MIS-103012-100, MIS-103106-100, MIS-103108-100, MIS-103112-100, MIS-103206-100, MIS-103208-100, MIS-103212-100.
U-40,	MIS-052806-40, MIS-052808-40, MIS-052812-40, MIS-052906-40, MIS-052908-40, MIS-052912-40, MIS-053006-40, MIS-053008-40, MIS-053012-40, MIS-053106-40, MIS-053108-40, MIS-053112-40, MIS-053206-40, MIS-053208-40, MIS-053212-40.
	MIS-102806-40, MIS-102808-40, MIS-102812-40, MIS-102906-40, MIS-102908-40, MIS-102912-40, MIS-103006-40, MIS-103008-40, MIS-103012-40, MIS-103106-40, MIS-103108-40, MIS-103112-40, MIS-103206-40, MIS-103208-40, MIS-103212-40.

Code expression:



2.7. 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.**

2.8. Basic UDI-DI

Product name	Basic UDI-DI
Mechanical Safety Insulin Syringes	697122740MISQA

2.9. Material

Component	Material
Barrel	Polypropylene (PP)
Plunger	Polypropylene (PP)
Protective shield	Polypropylene (PP)
Needle cap	Polyethylene (PE)
Piston	Polyisoprene rubber
Needle tube	X5CrNi18-10
Lubricant	Silicon oil
Needle tip	3 bevels

2.10. 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.

2.11. 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.

2.12. Sterilization

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

2.13. Shelf life

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

2.14. Storage requirements

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

2.15. Standards

Designation number and date	Title of standard (*Harmonised Standards*)
EN ISO 10993-1:2020	*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-4:2017	*Biological evaluation of medical devices —Part 4: Selection of tests for interactions with blood*
EN ISO 10993-5:2009	*Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-10: 2013	*Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*
EN ISO 10993-11:2018	*Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity*
EN ISO 10993-12: 2012	*Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*
EN ISO 11607-1:2020	*Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2020	*Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes*
EN ISO 11737-1:2018	*Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products*
EN ISO 11737-2:2020	*Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*
EN ISO 11135:2014	*Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices*

EN ISO 11138-1:2017	*Sterilization of health care products - Biological indicators - Part 1: General requirements*
EN ISO 11138-2:2017	*Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes*
EN ISO 14644-1:2015	*Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration*
EN ISO 14644-2:2015	*Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*
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 ISO 23908:2013	*Sharps injury protection-Requirements and test methods*
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

Content	Description
Unit package	Sterile barrier system is consisting of Blister film+ Dialyzing paper.
User package	Paper board
Transportation package	Double corrugated carton

3.2. Packaging specifications

Product Name	Box	Carton
Mechanical Safety Insulin Syringes	100 pcs	8 boxes
Note： *The quantity of package can be provided following up customer requirements.*		

4. Cautions and warnings

4.1. Cautions

Re-use of single use devices creates a potential risk of patient or user. It may lead to contaminationand/or limited functionality of the device may lead to injury ilness or death of the patient.
The product has a shield which lock in place after use to reduce the occurrence of needle sticks.
The needle cap color is used to indicate insulin concentration, red for U-40 and orange for U-100.Failure to heed this warning can result in a dosage error.

4.1. Warnings

Fixed needle
Do not use if package is damaged
Do not re-use
Discard it after use
Non-toxic/Non-pyrogenic

Note:

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This document can be changed without further notification.