Technical Documentation

Disposable Insulin Syringes

according to

Regulation 2017/745

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C/0	2021-08-10	MDR Regulations Update	Joanna Wang

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Chapter 1 DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSIRIES

1.1 Device description and specification

1.1.1 Name and address of the manufacturer

Name of Manufacturer:

Jiangsu Jichun Medical Devices Co., Ltd.

Address:

No. 98, Baiyang Bridge, Zhenglu Town, Tianning, Changzhou, Jiangsu 213111, China

Name of Factory/producer:

Jiangsu Jichun Medical Devices Co., Ltd.

Address:

No. 98, Baiyang Bridge, Zhenglu Town, Tianning, Changzhou, Jiangsu 213111, China

Brief introduction:

Jiangsu Jichun Medical Devices Co., Ltd, which established in 1988, is located at the Industrial Park of Zhenglu Town, Changzhou City, which is famous for the convenient transport action and enjoyable environment.

Our company occupies 40,000 square meters, consisting of modern purification plant with an area of 15,000 square meters.

We have a high technological background and advanced equipment. It mainly produces syringe, infusion set, hypodermic needle, insulin syringe, insulin pen needle, multi-way tube, components of infusion set, etc. it is a well-known medical device manufacturer.

In this field our company leads the way to pass the Health GMP certification of Brazilian ANVISA Ministry. Since then it has become the second enterprise which passes the

Brazilian GMP. In 2001 the company was credited as “Assured Labelling Product Enterprise” by China Medical Device Industry Association, Chinese Nursing Association and China Consumer Protection Foundation. Since 2002 it has achieved the quality system certification of ISO 9001/ ISO 13485 and CE product certification. It has also achieved the quality system for version certification of 2004 ISO 9001/ ISO 13485 and CE certification. In 2015 it has turned into a high-tech enterprise, accessing to provincial brand-name trademark. Our products are being sold well all over the world, including Europe, the Americas, Asia, Africa, the Middle East and other countries.

As member of Jichun Medical Equipment Co., Ltd, out staff will lay a strong foundation for markets, look forward to the future, persevere in marking efforts and have a lifelong ambition to move forward. Encouraging innovation in concept, technology and institution, we are going to seek business development in order to make unremitting efforts in human being’s health.

1.1.2 Device name and general description of the device

Device Name: Disposable Insulin Syringes

Types of syringes: Type3, Type7, Type 8

Model and Specification: U-40 (0.5ml, 1ml), U-100 (0.3ml, 0.5ml, 1ml)

Needle specification: 0.25(31G), 0.3(30G), 0.33(29G), 0.36(28G), 0.4(27G), 0.45(26G), 0.5(25G)

Trade Name: None

General description of the device:

The Disposable Insulin Syringes are designed for the subcutaneous injection of a dose of U-100 or U-40 insulin. The device consists of needle barrel, plunger, Plunger stopper, needle tube and upper and lower cap. The syringes will be available in 1mL, 0.5mL, 0.3mL, the needle will be available in various gauge sizes being 31G, 30G, 29G, 28G, 27G, 26G, 25G and in various needle length being 6mm to 25mm.

The Disposable Insulin Syringes is sterilized by EO. The shelf-life of the product is 5 years.

1.1.3 Intended use

Disposable Insulin Syringes is a device that is used to inject insulin subcutaneously into the human body.

1.1.4 Intended users

Professional doctors

Patients after training by doctors.

1.1.5 Intended Patient populations

From children to elderly.

1.1.6 Basic UDI-DI

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

UDI-DI: The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the ‘access key’ to information stored in a UDI database.

UDI-PI: The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

A UDI shall be assigned to the device itself or its packaging. The UDI shall contain two parts: a UDI-DI and a UDI-PI. The UDI-DI shall be unique at each level of device packaging.

Basic UDI-DI: U-100:69586949FYDSZSQ001G8

U-40:69586949FYDSZSQ002GA

1.1.7 The disease status to be diagnosed/targeted/monitored

Patients who need hypodermic inject insulin.

1.1.8 Contraindications

None

1.1.9 Cautions &Warnings

1. Before use, please check the integrity of the single package, single package leakage, damage and protective cover off, prohibit the use.

2. This product has been sterilized and used only for one-time use. It will be destroyed after use and the waste will be disposed of according to local government regulations.

3. Do not use with paraldehyde.

4. Inject the human body immediately after aspirating the insulin solution.

5. This product is sterilized by EO for a period of validity of 5 years. When the product is in use, it is valid at the time of expiration of the package seal, and it is forbidden

to use after expiration.

6. The injection site should be loose skin, such as upper arm, thigh, buttocks and abdomen. The injection site should alternate alternately. The same site cannot be injected twice in two weeks. Each injection site should be at least separated from the last injection site. 1cm or so.

7. Used by patients who is trained by doctors or professional doctors.

1.1.10 Description of the principle

A syringe is a simple reciprocating pump consisting of a plunger (actually a Plunger stopper) that fits tightly within a cylindrical tube (called a barrel). The plunger can be linearly pulled and pushed along the inside of the tube, allowing the syringe to take in and expel liquid or gas through a discharge orifice at the front (open) end of the tube. The open end of the syringe may be fitted with a hypodermic needle, a nozzle, or a tube to help direct the flow into and out of the barrel. Syringes are frequently used in clinical medicine to administer injections, infuse intravenous drugs into the bloodstream, apply compounds such as glue or lubricant, and draw/measure liquids.

1.1.11 Conformity assessment procedure

Jiangsu Jichun Medical Devices Co., Ltd. has established and applies a quality management system for manufacturing and distribution of Disposable Insulin Syringes, in accordance with EN ISO 13485 and Regulation (EU) 2017/745. The conformity assessment procedure would be MDR Annex IX (Chapter I+III+Sec.4) according to MDR Article 52.

Name: TÜV Rheinland LGA Products GmbH

Address: Tillystraße 2, 90431 Nürnberg Germany

Country: Germany

CE identifier: 0197

The copy of the certificates is given in the following attachments:

- Folder 01# MDD Annex V Certificate # No. DD 60150044 Rev.01, issued on 2020-06-17, valid until 2022-10-16;

- Folder 01# EN ISO 13485 certificate # No. SX 60150047 Rev.01, issued on 2020-06-17, valid until 2023-06-16;

1.1.12 Rationale for the qualification of the product as a device

The Disposable Insulin Syringes is intended by the manufacturer to be used for human beings treatment or alleviation diseases.

1.1.13 Classification rule(s)

Device Name: Disposable Insulin Syringes

According to Regulation (EU) 2017/745(MDR) Appendix VIII Rule 6, the Disposable Insulin Syringes is classified as a Class IIa medical device.

JUSTIFICATION FOR THE CLASSIFICATION RULE(S)	RATIONALE	RISK CLASS
RULE 6: All surgically invasive devices intended for transient use are classified as class IIa.	The Disposable Insulin Syringe is a single use and surgically invasive medical device, It is intended for continuous use for less than 60 minutes, which belongs to Transient Use.	Class IIa

1.1.14 Explanation for novel features

None

1.1.15 Description of the accessories

None.

1.1.16 Description of the Variant configurations/ variants

Type of syringes: Type3, Type7, Type8
Model and specification: U-40 (0.5ml, 1ml), U-100 (0.3ml, 0.5ml, 1ml)
Needle specification: 0.25(31G), 0.3(30G), 0.33(29G), 0.36(28G), 0.4(27G), 0.45(26G), 0.5(25G)
Notes:

- Colour code is identified as the insulin unit. Red is used for U-40 insulin syringe, and its printing scale is red; Orange is used for U-100 insulin syringe.
- The colour code for insulin syringe is shown on the upper and lower caps.
- Red and orange are only identified for the unit of insulin syringe, not for other identifications.
- The barrel of insulin syringe shall be marked with the following information: an appropriate graduated scale; a text indicating the insulin concentration for which the insulin syringe is designed to hold, e.g. the text “U-40 insulin” or “U-100 insulin”; the word “unit” or “I.U”and the total graduated capacity of the insulin syringe is in “ml”.
- U-40 and U-100 are indicated as insulin concentration. U-40 indicates to be used for injecting insulin with concentration 40unit/ml, U-100 indicates to be used for injecting insulin with concentration 100unit/ml. The graduated capacity on the barrel of insulin syringe indicates the insulin volume, the graduated capacities of U-40 and U-100 are converted as following table:

Type of syringes	model	Unit	Capacity ml	Min. scale length mm	Scale interval/ unit	corresponding graduated capacity ml	Scale colour	Cap colour
Type 3	Siamese	U-40	0.5mL	43	0.5	0.0125	red	NO
			0.5mL	43	1	0.025		
			1mL	50	1	0.025		
		U-100	0.3mL	41	0.5	0.005	black	NO
			0.3mL	41	1	0.01		
			0.5mL	43	1	0.01		
			1mL	57	1	0.01		
			1mL	57	2	0.02		
Type 7	Siamese	U-40	0.5mL	43	0.5	0.0125	red	red
			0.5mL	43	1	0.025		
			1mL	50	1	0.025		
		U-100	0.3mL	41	0.5	0.005	black	Orange
			0.3mL	41	1	0.01		
			0.5mL	43	1	0.01		
			1mL	57	1	0.01		
			1mL	57	2	0.02		
Type 8	Siamese	U-40	0.5mL	43	0.5	0.0125	red	red
			0.5mL	43	1	0.025		
			1mL	50	1	0.025		
		U-100	0.3mL	41	0.5	0.005	black	Orange
			0.3mL	41	1	0.01		
			0.5mL	43	1	0.01		
			1mL	57	1	0.01		
			1mL	57	2	0.02		

Type 3: Syringe having a 6 % (Luer) male conical fitting, and supplied with a detached or detachable needle and packaged in a unit container.

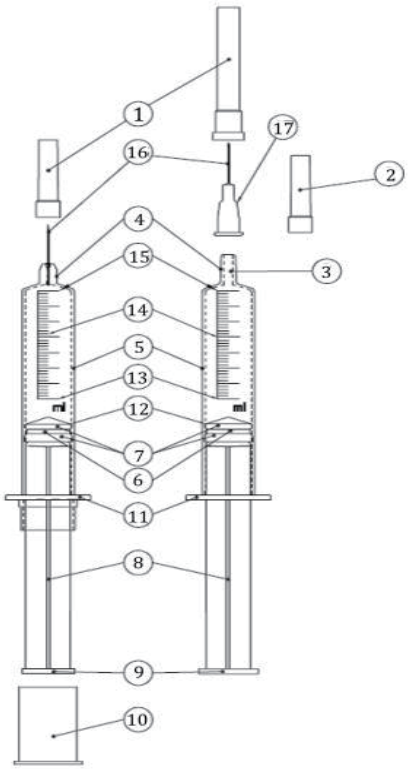
Type 7: Syringe with fixed needle tube and packaged in a unit container.

Type 8: Syringe with fixed needle tube and fitted with protective end caps.

1.1.17 Description of the key functional elements

Product components:

The Disposable Insulin Syringes mainly consist of needle barrel, plunger, Plunger stopper, needle tube and upper and lower cap. The Disposable Insulin Syringes references are in figure 1:



Key

1	needle cap	10	plunger cap
2	nozzle cap	11	finger grips
3	nozzle lumen	12	fiducial line
4	nozzle	13	nominal capacity
5	barrel	14	graduation lines
6	plunger stopper	15	zero line
7	seals	16	needle tube
8	plunger	17	hub
9	push-button		

Note This figure is only intended to be illustrative of the components of a syringe. The piston might or might not be of integral construction and might incorporate more than one seal.

Figure 1, Disposable Insulin Syringes

Product Picture:

Type 3: Syringe having a 6 % (Luer) male conical fitting, and supplied with a detached or detachable needle and packaged in a unit container.

Type 7: Syringe with fixed needle tube and packaged in a unit container.

Type 8: Syringe with fixed needle tube and fitted with protective end caps

1.1.18 Description of the raw material

No.	Name	Material	Material Specification	Applicable Standard	Manufacturers
1.	Barrel	PP	RJ766MO	/	远大石化有限公司
2.	Plunger	PP	1100N	/	常州化工轻工材料总公司
3.	Needle hub	PP	1100N	/	常州化工轻工材料总公司
4.	Needle cap	PP	R3260T	EN ISO 23908: 2011	浙江鸿基石化有限公司
5.	Nozzle cap	PE	HD52518	/	江苏尚邦国际贸易有限公司
6.	Plunger cap	PE	HD52518	/	江苏尚邦国际贸易有限公司
7.	Plunger stopper	/	/	/	常州京林
8.	Needle tube	SUS304 stainless steel	/	EN ISO 9626: 2016	浙江京环

1.1.19 Description of the body contact

No.	**Applied Part Name**	**Material Designation**	**Nature of Body contact**	**Contact duration**
1	Barrel	PP	External communicating devices: Blood path, indirect	Limited exposure: Less than 24 hour
2	Plunger	PP	External	Limited exposure:

No.	Applied Part Name	Material Designation	Nature of Body contact	Contact duration
			communicating devices: Blood path, indirect	Less than 24 hour
3	Needle hub	PP	External communicating devices: Blood path, indirect	Limited exposure: Less than 24 hour
4	Needle cap	PP	Non-contract	/
5	Nozzle cap	PE	Non-contract	/
6	Plunger cap	PE	Non-contract	/
7	Plunger stopper	/	External communicating devices: Blood path, indirect	Limited exposure: Less than 24 hour
8	Needle tube	SUS304 stainless steel	External communicating devices: Blood path, direct	Limited exposure: Less than 24 hour

1.1.20 Product Specifications

1. Sterile single-use syringes, with or without needle, for insulin (According to EN ISO 8537:2016)

1.1 General requirements (ISO 8537:2016 Clause 5.1)

The general requirements listed below are considered to be design guidelines for manufacturers.

a) Given the likelihood that multiple insulin concentrations and concentration-specific syringes will exist in a particular country or locality, the manufacturer shall develop risk mitigation strategies to minimize the occurrence of “wrong dose” medication errors.

b) The syringe shall indicate, through visual means, the insulin concentration it is intended to contain.

The insulin syringes should also indicate, through non-visual means (e.g. tactile) , the insulin concentration it is intended to contain.

c) Syringes designed to contain a specific concentration of insulin (e.g. U-100) shall be adequately differentiated visually from other dedicated syringes. This differentiation shall be determined based on a risk assessment and confirmed through usability validation testing.

d) The syringe and needle should be free from defects affecting safety, serviceability for their intended use, and appearance.

e) The syringe scale shall be graduated in increments corresponding to units of only one concentration of insulin. The syringe scale graduation and numbering increments shall be determined through risk analysis and confirmed through usability validation testing.

NOTE 1 Annex H offers guidance from prior versions of ISO 8537 for graduation and numbering increments on U-40 and U-100 syringes.

f) The nominal capacity of the syringe shall be designated in millilitres (ml) .

g) The tolerances on the graduated capacity shall be in accordance with Table H.1.

h) Syringes indicated for use with devices or accessories that provide automated functions (e.g.needle insertion and retraction) shall comply with applicable requirements of ISO 11608-1 and ISO 11608-5.

i) Syringes with integrated or add-on sharps protection shall comply with ISO 23908.

j) Syringes with Luer attachment features shall comply with ISO 80369-7.

k) The length of the barrel shall be sufficient to allow the expulsion of any air bubbles without affecting the syringe’s nominal capacity.

NOTE 2 Compliance with this requirement may be demonstrated, for example, by meeting the requirements in 5.6.1.

l) The syringe’s finger grips shall be of adequate size, shape and strength for the intended purpose.The design specifications for the finger grips shall be determined through risk analysis and confirmed through usability validation testing.

m) The materials used in the syringe shall be tested and qualified according to ISO 10993-1.

n) The self-contained syringes with sterile interiors and syringes provided in its unit packaging shall have been subjected to a validated sterilization process.

NOTE 3 For testing these properties, tne manufacturer may use an extract, as specified in Annex G.

1.2 Material selection (ISO 8537:2016 Clause 5.2)

With regard to material selection,

— materials used for fabrication of the syringe barrel shall be of sufficient clarity to enable dosages to be read and for air bubbles to be seen without difficulty, and

— materials used for fabrication of syringes and needles (including lubricant) and packaging shall not, in their final form after sterilization and under conditions of intended use, adversely affect the efficacy, safety and acceptability of insulin

preparations. The fabrication materials shall also not be affected, either physically or chemically, by insulin preparations.

1.3 Colour coding (ISO 8537:2016 Clause 5.3)

Colour coding of syringes intended for dedicated use with specific insulin concentrations is as follows.

— The barrel of the insulin syringe shall be clear, with graduation markings of a colour that contrasts clearly with the syringe.

— The colour used to indicate the insulin concentration shall appear on at least one component of the syringe (e.g. needle cap, plunger cap, plunger, a portion of the barrel that does not interfere with visibility of the graduation lines) .

— For insulin syringes with fixed needles, the colour of the needle cap shall be the colour designated for the insulin concentration.

— The colour coding used on the syringes shall be repeated and explained on the user packaging and, if applicable, on the unit packaging.

NOTE 1 The presence of colour coding on a syring or ackage does not absolve the user of the responsibility to check the marked insulin concentration of the syrings.

— No additional colours,other than black and white,shall be used on the syringe barrel.

NOTE 2 In acknowledgement that established syringes on the market use red to indicate the U40 insulin strength on the barrel, these syringes are exempted.

— The dedicated colours used to indicate insulin concentration shall be the following;

    — red for U40;

    — Orange for U100.

The following colours are given in order to prevent regional variation and to prevent the use of the same colour for different concentrations and different colours for the same concentration;

— light blue U200;

—yellow for U300;

—purple for U400;

—green for U500.

For the newly introduced colours and for any new co;our selected, the complete information provided for the user shall be assessed for risk according to ISO 14971 and for usability according to IEC 62366-1.

NOTE 3 These colour restrictions do not apply to detachable needles.

1.4 Extraneous matter (ISO 8537:2016 Clause 5.4)

1.4.1 General(ISO 8537:2016 Clause 5.4.1)

The surfaces of the syringe and needle that come in contact with insulin shall be clean and free from extraneous matter.

NOTE Complinance with this requirement will be determined through inspection by an individual with normal vision (or corrected-to-normal vision),without magnification.

1.4.2 Limits for acidity or alkalinity(ISO 8537:2016 Clause 5.4.2)

Exposure of distilled water to the finished syringe product shall not change its pH value by more than one unit.

Compliance with this requirement may be demonstrated by preparing the solutions described in Annex A. The results shall show that the pH value of the syringe assessment fluid is within one pH unit of the pH value of the control fluid.

NOTE The PH value of both solutions may be determined with a laboratory potentiometric PH meter using a general purpose electrode.

1.4.3 Limits for extractable metals(ISO 8537:2016 Clause 5.4.3)

Exposure of distilled water to the finished syringe product shall not change its content of metals by more than a combined total of 5 mg/kg of lead, tin, zinc and iron; the cadmium content shall be less than 0,1 mg/kg.

Compliance with this requirement may be demonstrated by preparing the solutions described in Annex A and testing them using a recognized micro-analytical method, for example, by an atomic absorption method.

1.5 Lubrication (ISO 8537:2016 Clause 5.5)

1.5.1 Lubrication of syringes (ISO 8537:2016 Clause 5.5.1)

If the interior surfaces of the syringe, including the plunger stopper, are lubricated, the lubricant shall not form pools of fluid on the interior surface of the syringe.

1.5.2 Lubrication of needle tube (ISO 8537:2016 Clause 5.5.2)

If the needle tube is lubricated, the lubricant shall not be visible to an individual with normal or corrected-to-normal vision as droplets of fluid on the outside surfaces of the needle tube.

1.6 Dimensions (ISO 8537:2016 Clause 5.6)

1.6.1 Barrel and plunger stopper (ISO 8537:2016 Clause 5.6.1)

The barrel length shall be such that the syringe has a usable capacity of either 10 % more than the nominal capacity or 3 mm of plunger travel beyond the scale marking, whichever is less.

1.6.2 Finger grips (ISO 8537:2016 Clause 5.6.2)

The open end of the barrel shall be provided with finger grips that prevent the syringe from rolling when the axis of the barrel is placed perpendicular to the incline of a flat surface angled at 10° from horizontal.

1.7 Plunger/ plunger stopper (ISO 8537:2016 Clause 5.7)

1.7.1 General (ISO 8537:2016 Clause 5.7)

The design of the plunger and push-button on the end of the plunger shall be such that when the is held in one hand, the plunger can be depressed by the thumb of that hand. The plunger stopper not become detached from the plunger during the test described in Annex B.

The projection of the plunger and the configuration of the push-button should be such as to enable plunger, when in the fully inserted position, to be grasped and drawn back without difficulty.

1.7.2 Fit of plunger stopper in barrel (ISO 8537:2016 Clause 5.7)

When the syringe is filled with water and then held in both vertical orientations (i.e. with the needle end either up or down) , the plunger shall not move by the force of gravity acting on the combined mass of the plunger and the water in the barrel. When a needle is secured to the syringe in accordance with the instructions provided by the manufacturer, the force required to initiate movement of the plunger to expel water from the syringe shall not exceed 15 N.

NOTE Compliance withe this requirement can be demonstrated using the procedures described in Annex C.

The fit of the plunger stopper in the barrel should be such that the plunger stopper slides smoothly throughout the full range of its travel within the barrel.

1.8 Nozzle (ISO 8537:2016 Clause 5.8)

1.8.1 Conical fitting (ISO 8537:2016 Clause 5.8.1)

The male conical fitting of the syringe nozzle on syringe types 1, 2, 3 and 4 shall comply with the requirements of ISO 594-1.

1.8.2 Position of nozzle on end of barrel (ISO 8537:2016 Clause 5.8.2)

The syringe nozzle shall be situated centrally, i.e. shall be co-axial with the barrel.

1.9 Needle tubing and needles (ISO 8537:2016 Clause 5.9)

1.9.1 Needles for syringe types 3 and 4 (ISO 8537:2016 Clause 5.9.1)

Needles for syringe types 3 and 4 shall be in accordance with ISO 7864.

1.9.2 Needle tubing for syringe types 5, 6, 7 and 8 (ISO 8537:2016 Clause 5.9.2)

Needle tubing for syringe types 5, 6, 7 and 8 shall be in accordance with ISO 9626.

The needle point shall be in accordance with ISO 7864.

The needle length shall be measured as shown in Figure 1 and the tolerance of the needle length shall be within ±1,25 mm.

1.9.3 Bond between hub and needle tube (ISO 8537:2016 Clause 5.9.3)

The bond between the hub and needle tube shall withstand at least the shearing forces shown in Table 1.

Nominal outside diameter of needle (mm)	Minimum shearing strength
≥0,33	22 N (5 lbs)
<0,33	11 N (2,5 lbs)

1.10 Standard test environmental conditions (ISO 8537:2016 Clause 5.10)

Unless otherwise specified, measurements shall be performed under the following atmospheric conditions:

— temperature between 18 °C and 28 °C;

— relative humidity between 25 % RH and 75 % RH.

Testing shall be performed after samples have been stored under these conditions for at least 4 h.

1.11 Performance of assembled syringe (ISO 8537:2016 Clause 5.11)

1.11.1 Dead space (ISO 8537:2016 Clause 5.11.1)

Dead space should be minimized to reduce waste and transmission of infectious agents.

The dead space shall not exceed the limits given in Table 2.

NOTE Compliance with this requirement may be demonstrated using the methods described in Annex D.

Table 2 — Maximum dead space

Type of syringe	Maximum dead space (ml)
1 and 2	0,07
3 and 4	0,10
5 and 6	0,02
7 and 8	0,01

1.11.2 Freedom from leakage at needle (ISO 8537:2016 Clause 5.11.2)

There shall be no leakage of water sufficient to form a falling drop within 30 s from the junction point between the syringe nozzle and the needle hub or the junction point between the syringe and the needle tube, as appropriate.

NOTE 1 Compliance with this requirement may be demonstrated using the method described in Annex E.

NOTE 2 Compliance with this requirement may be demonstrated using the method described in Annex F.

1.11.3 Freedom from leakage past plunger stopper (ISO 8537:2016 Clause 5.11.3)

There shall be no leakage of water past the Plunger stopper seal.

NOTE 1 Compliance with this requirement may be demonstrated using the method described in Annex E.

There shall be no leakage of air past the plunger stopper seal and there shall be no drop in the manometer reading.

NOTE 2 Compliance with this requirement may be demonstrated using the method described in Annex B.

1.2 Previous and similar generation of the device

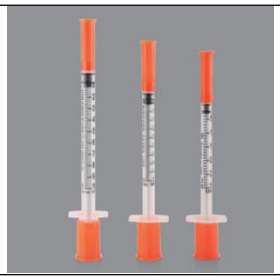
Overview of the previous generations of the device produced by the manufacturer:

- None.

Overview of identified similar devices available on the Union or international markets:

At present, domestic manufacturers of similar products include: At present, in the union or international market Sterile insulin syringes for single use brands include Terumo Medical Canada Inc, Becton, Dickinson and Company, Zibo Eastmed Healthcare Products Co., Ltd, Shantou Wealy Medical Instrument Co., Ltd., Zhejiang INI Medical Devices Co., Ltd., Nanchang Maidikang Medical Instrument Factory, Changzhou Kangfulai Medical Thing Co., Ltd., etc.

Equivalent device information	

Manufacturer	Changzhou Kangfulai Medical Thing Co., Ltd.	Becton Dickinson and Company
CE certificate	DD 60122549 0001	CE 0050 252.128
Product Name	Sterile insulin syringes for single use	BD Insulin Syringes with the BD Ultra-Fine™ needle
Product Picture		
Types of syringes	Type 3	Type 7, Type 7
Contents	Syringe, with fixed needle (Size 29G,30G,31G, 32G), double caps	Syringe，with fixed needle (Size 27G,28G,29G,30G,31G) ,double caps

1.3 EC Authorized Representative

Since the registration address of Jiangsu Jichun Medical Devices Co., Ltd. is located outside the area of EEA, Switzerland and Turkey, a single authorized representative located in EEA, Switzerland and Turkey is appointed to Disposable Insulin Syringes, which is:

Name:	Caretechion GmbH
Address:	Niederrheinstr 71, 40474 Duesseldorf, Germany
Tel:	+49 211 23 98 90 0
Fax:	+49 211 23 98 90 99
Dimdi No.:	DE/0000048026
SRN:	DE-AR-000005946
E-mail:	info@caretechion.de

The agreement with the appointed EU authorized representative has been signed and is provided in the attachment:

- Folder 1 # JC/QS9.7f-01-01_EU Authorized Representative Agreement

1.4 EMDN code

EMDN Code: A020106, INSULIN SYRINGES W/O FIXED NEEDLES, SINGLE-USE

1.5 Declaration of conformity

Declaration of Conformity

- Folder1# DOC for Disposable Insulin Syringes, file # JC/QS9.7f-01-02.

Chapter 2 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

On the label of the device, the symbols and information shall take consideration of the following requirements:

- Annex I of Regulation (EU) 2017/745
- EN 1041:2008+A1:2013
- EN ISO 15223-1:2021
- EN ISO 8537:2016

The draft labels are given in the attachments:

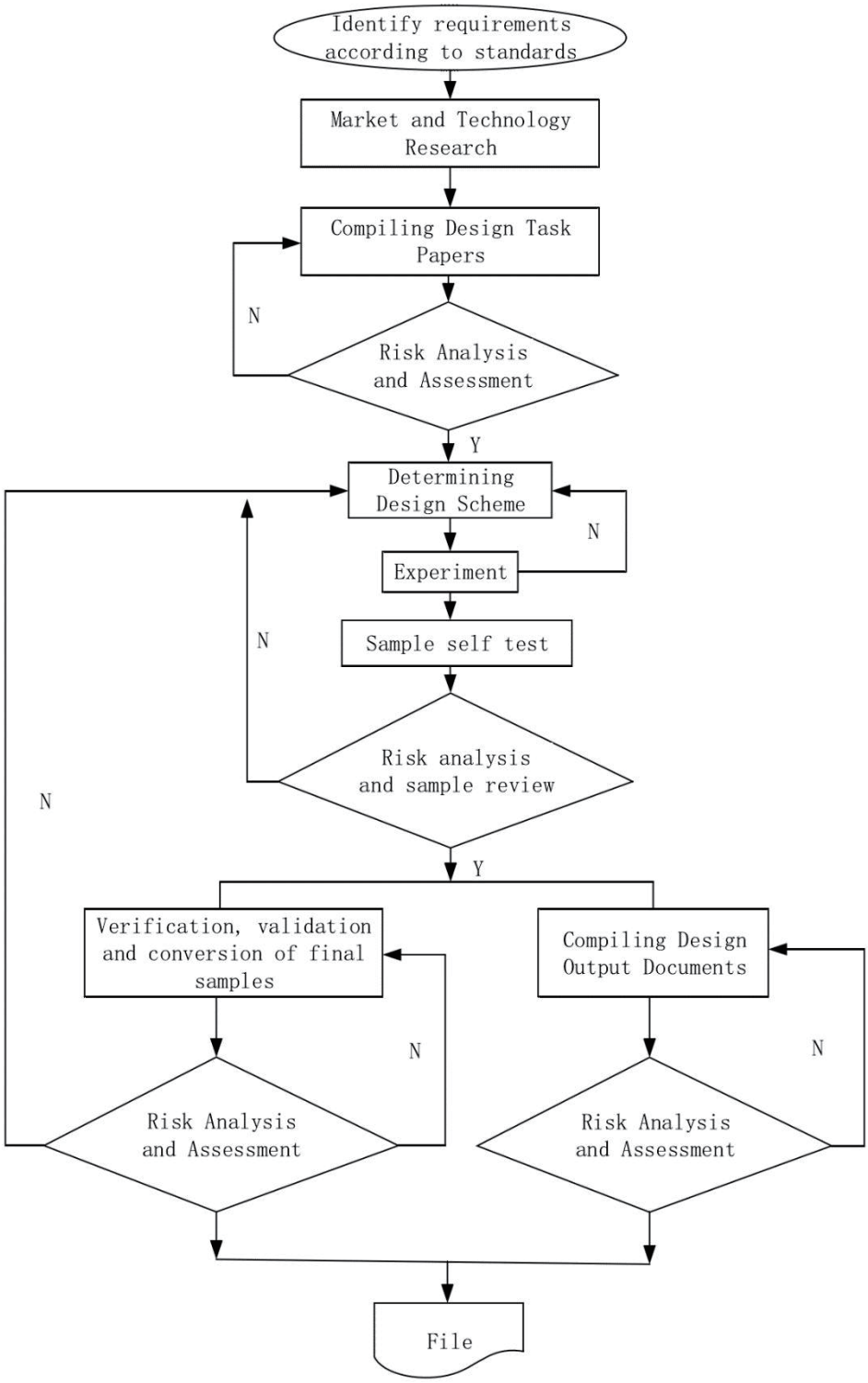
☒ Draft label for Disposable Insulin Syringes: Folder 2 # JC/QS9.7f-02-01.

☒ Draft IFU for Disposable Insulin Syringes: Folder 2 # JC/QS9.7f-02-02.

Chapter 3 DESIGN AND MANUFACTURING INFORMATION

3.1 Design Information

3.1.1 Design and Development flow chart



3.1.2 Design and Development Control

(1) Design & development planning: Technology dept. should provide <project development requisition>, after approved by general manager, technology dept. start to conduct design planning.

(2) Design & development inputs: Technology dept. is responsible for collection of product requirements, and compilation of the design & development inputs based on the requirements. Design & development input shall at least include the following items: Product function/performance requirements, where applicable, the identification of international standards; Where applicable, product microbiological requirements, Product packaging, preservation and distribution requirements; Legal / registration requirements; Labeling requirements. Design and development input shall be documented.

(3) Design & development outputs: Design export files should be expressed by validations to the design development inputs. Final Design & Development outputs shall include: Technical spec., standard operation procedures, Material qualified suppliers and suppliers of any outsourced process, and quality agreement with those suppliers. Standard samples, Inspection criteria, including sampling protocol, test method and acceptance criteria, Labeling design, including instruction for use.

(4) Design & development review: Project Manager is to organize review of the outputs of each design stages according to the design & development plan. The participants attending design review usually include Chief Engineer, Technology personnel, QA personnel, Production personnel; customers may attend the meetings when necessary.

(5) Design & development verification: Project manager is responsible for organization of relative functions to work out the design verification protocol. Design verification results shall be reviewed for objective evidences that the design outs fulfill the design input requirements

(6) Design & development validation: The purpose of design validation is confirmation by examination and provision of objective evidence that the design output can fulfill device intended use. Design validation is achieved by: Product simulated use, including product packaging distribution test; Actual use of product trial production samples, including clinical test; the comprehensive examination or evaluation by customers; Retrospective validation of equivalent device, including clinical data compilation. The records of design validation shall be maintained.

(7) Design transfer: Design transfer typically includes the following activities: According to the data and information from the design outputs, finalize the other part of DMR, such as inspection criteria, Process development, establishment of applicable and reliable production process specification, including process validation, Necessary training etc.

The product design drawing and purchasing list as two parts of the output of the Design and Development is presented as below:

Disposable Insulin Syringes drawings

Product drawings list		
Device name	Drawing No.	Document name
0.3ml insulin	JC/DRWYDS-0.3G-00	General assembly drawing of 0.3ml insulin
	JC/DRWYDS-0.3G-01	0.3ml insulin core
	JC/DRWYDS-0.3G-02	0.3ml insulin overcoat
	JC/DRWYDS-0.3G-03	0.3ml Plunger stopper
	JC/DRWYDS-DG-04	Needle tube
	JC/DRWYDS-01G-05	insulin upper cap
	JC/DRWYDS-0.3G-06	Printing scale
	JC/DRWYDS-01G-07	Lower cap with insulin
0.5ml insulin	JC/DRWYDS-0.5G-00	General assembly drawing of 0.5ml insulin
	JC/DRWYDS-0.5G-01	0.5ml insulin core
	JC/DRWYDS-0.5G-02	0.5ml insulin overcoat
	JC/DRWYDS-0.5G-03	0.5ml Plunger stopper
	JC/DRWYDS-DG-04	Needle tube
	JC/DRWYDS-01G-05	insulin upper cap
	JC/DRWYDS-0.5G-06	Printing scale
	JC/DRWYDS-01G-07	Lower cap with insulin
1ml insulin	JC/DRWYDS-01G-00	General assembly drawing of 1ml insulin
	JC/DRWYDS-01G-01	1ml insulin core
	JC/DRWYDS-01G-02	1ml insulin overcoat
	JC/DRWYDS-01G-03	1ml Plunger stopper
	JC/DRWYDS-DG-04	Needle tube
	JC/DRWYDS-01G-05	insulin upper cap

	JC/DRWYDS-01G-06	Printing scale
	JC/DRWYDS-01G-07	Lower cap with insulin
0.3ml, 0.5ml, 1ml insulin	JC/DRWYDS-BZ-01	Blister packaging drawin
	JC/DRWYDS-BZ-02	primary package of insulin
	JC/DRWYDS-BZ-03	middle package of insulin
	JC/DRWYDS-BZ-04	external package of insulin

Purchase list

No.	Name	Material	Material Specification	Applicable Standard	Manufacturers
1.	Barrel	PP	RJ766MO	/	远大石化有限公司
2.	Plunger	PP	1100N	/	常州化工轻工材料总公司
3.	Needle hub	PP	1100N	/	常州化工轻工材料总公司
4.	Needle cap	PP	R3260T	EN ISO 23908: 2011	浙江鸿基石化有限公司
5.	Nozzle cap	PE	HD52518	/	江苏尚邦国际贸易有限公司
6.	Plunger cap	PE	HD52518	/	江苏尚邦国际贸易有限公司
7.	Plunger stopper	/	/	/	常州京林
8.	Needle tube	SUS304 stainless steel	/	EN ISO 9626: 2016	浙江京环

3.1.3 Design and Development Process

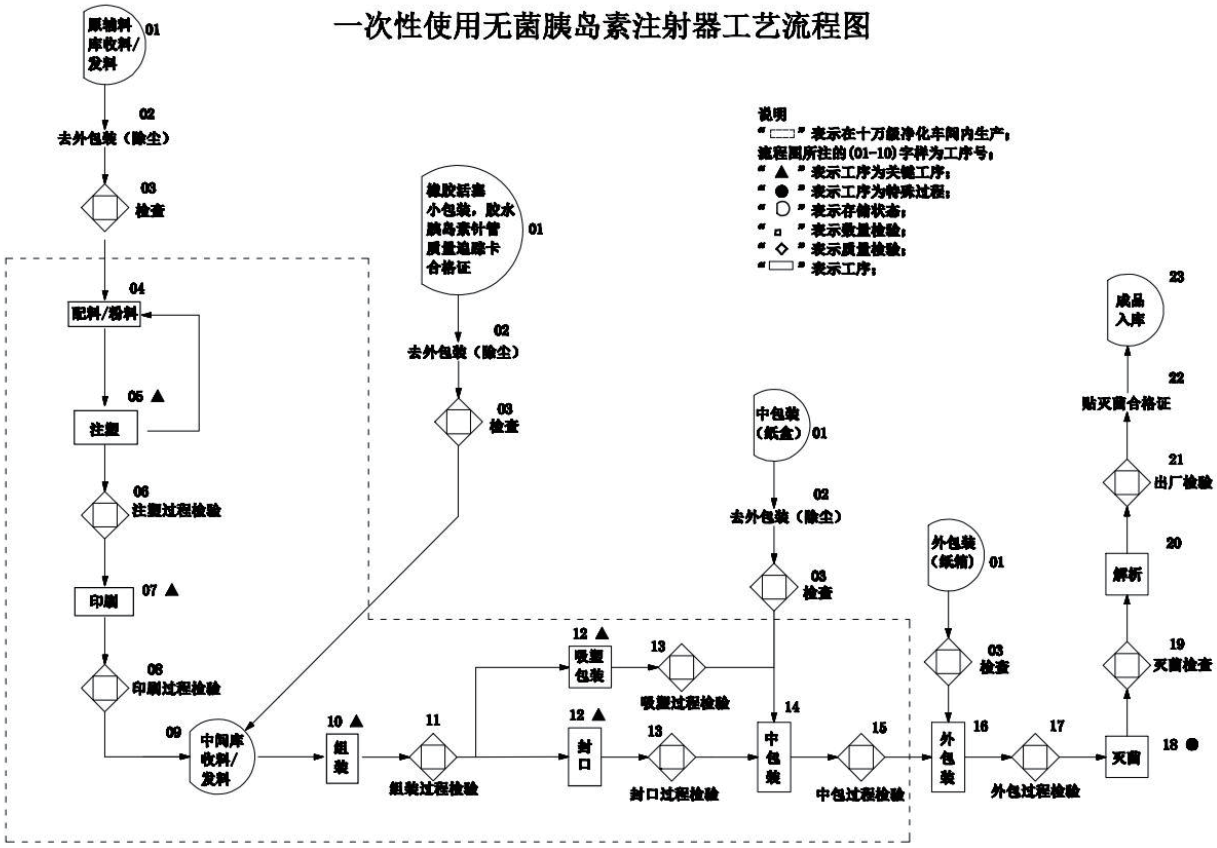
We controlled the design & development processes in accordance with the requirements for design and development, and kept relative records.

3.1.4 Design and Development Files

We maintain a design and development file for each medical device type or medical type or medical. This file include or reference records generated to demonstrate conform.

3.2 Manufacture Information

3.2.1 Production Process Flow Chart



Notes:

1. □ is Class 8 clean area;

2. Injection molding/ printing, Assembly, Primary packaging are key process;

3. EO sterilization is a special process;

Plant location:

No. 98, Baiyang Bridge, Zhenglu Town, Tianning, Changzhou, Jiangsu 213111, China

Sterilization location:

No. 98, Baiyang Bridge, Zhenglu Town, Tianning, Changzhou, Jiangsu 213111, China

3.2.2 Key and Special processing validation

In the production process of the Disposable Insulin Syringes, EO sterilization is special processes and Injection molding/ printing, Assembly, Primary packaging are Key processes. Quality control points have been set for the above special and key processes. This process Injection molding/ printing, storage, assembly and primary

packaging are required in ISO Class 8 clean area. The details process refers to the associated documents of SOP.

Validation of the special and key processes has been conducted and the approved parameters are monitored during routine production. Annual revalidation or reviews will also be performed and documented to evaluate the efficacy of the previous validation result.

3.2.3 Production environment

The environment in ISO Class 8 clean room workshops should meet the requirements specified by ISO 14644 to prevent the product from contamination during production, fine cleaning, assembling and primary packaging. Relevant personnel are required to implement it strictly while maintaining relevant control records. The major control requirements are as follows:

Environmental monitoring requirements for ISO class 8 clean rooms

Monitoring item	Instrument and methods	Technical requirement		Monitoring positions	Monitoring frequency
Temperature	Thermometer	18℃~28℃		Indoor	1 Time/Shift
Humidity	Thermometer	45%Rh~65%Rh			
Air Change Rate	Anemograph	≥15 times/H		Indoor Air Inlet	1 Time/Month
Static pressure difference	Differential Pressure Gauge	≥5Pa (between clean rooms (areas) of different class)		High To Low Pressure Area	1 Time/Month
		≥ 10Pa (between clean room (area) and outdoors)			
		≥5Pa (Adjacent between clean room (area)			
Airborne particle	Particle Counter	≥0.5um	≥5um	By Rule	1 Time/Season
		≤3500000 particles/m^3	≤20000 particles/m^3		
Airborne microbe	Airborne microbe tester	≤500cuf/ m^3		By Rule	1 Time/Season
Settling microbe	culture dish	≤ 10 CFU/4h, culture dish ф90mm,Exposure time not more than 4 hours, indicated by the average number of colonies		By Rule	1 Times/Week

☒ Folder 3# SSMT-R-2020-02088-01A Clean room Environment monitoring report

3.2.4 Technical Documents list

NO.	project name	document No.	document name
1	Production Process	JC/WI7.5.1d/04	Disposable Insulin Syringes Process Flow Chart
		JC/WI7.5.1d/04	Disposable Insulin Syringes QC Worksheet
2	Device specification	JC/DRWYDS-#	Composition and accessories list
		JC/DRWYDS-#	Product and packaging drawings
		JC/QS4.2.3d-2-3	Technical requirements for Disposable Insulin Syringes
		JC/QR6.3b/03	Production equipment list
3	Production process specification	JC/QSP7.5.1a	Production process control procedure
		JC/WI7.5.11/01	Raw material warehouse management system
		JC/WI7.5.11/02	Intermediate warehouse management system
		JC/WI7.5.11/03	Finished warehouse management system
		JC/WI6.3b/02/#	Injection molding equipment operating procedure
		JC/WI6.3b/05/05	Disposable Insulin syringes automatic assembly machine equipment operating procedure
		JC/WI6.3b/05/02	Operating procedures for Disposable needles
		JC/WI6.3b/08	Ethylene oxide sterilizer equipment operating procedure
		JC/WI7.5.1d/04	Work Instructions of Disposable Insulin Syringes
		JC/QSP 6.4a	Environmental control procedure
		JC/QSP 6.4b	Process hygiene control procedure
		JC/QSP6.4.2	Pollution control procedure
		JC/WI6.3a/01	Process water management regulation
		JC/WI6.3b/01	Water plant operating procedure
		JC/WI6.3b/12	Ultrasonic cleaning machine equipment operating procedure
		JC/QSP 7.5.1b	Product history control procedure
		JC/QSP 7.5.1c	Product release control procedure
		JC/WI6.3b/09	Screw air compressor equipment operating procedures
		JC/WI6.3b/10	Air conditioning and air supply system equipment operating procedures
		JC/WI7.5.1a	Clearance management regulation
		JC/WI7.5.1b	Work station appliances management regulation
		JC/WI7.5.1c	Batch number management regulation
		JC/QSP 8.2.6	Product monitoring and measurement

			control procedure
4	Quality assurance procedure and specifications	JC/QSP 8.3	Control of nonconforming product procedure
		JC/QSP 8.4	Data analysis control procedure
		JC/QSP 7.4a	Purchasing control procedure
		JC/QSP 7.6	Monitoring and measuring device control procedure
		JC/QSP 8.2.6	Product monitoring and measurement control procedure
		JC/QSP 8.3	Control of nonconforming product procedure
		JC/QS8.2.6a/02/01	PP incoming inspection specification
		JC/QS8.2.6a/02/02	PE incoming inspection specification
		JC/QS8.2.6a/03/01	Plunger stopper Incoming inspection specification
		JC/QS8.2.6a/04/01	Medical Dialysis Paper Purchase Inspection Specification
		JC/QS8.2.6a/04/04	Carton incoming inspection specification
		JC/QS8.2.6a/04/05	Corrugated box purchase inspection specification
		JC/QS8.2.6a/08/01	Needle tip glue inspection specification
		JC/QS8.2.6a/09	Diluent purchase inspection specification
		JC/QS8.2.6a/11	Ethylene oxide incoming inspection specification
		JC/QS8.2.6a/12	Ethylene oxide chemical indicator card purchase inspection specification
		JC/QS8.2.6a/13	Ethylene oxide bio-indicator incoming inspection specification
		JC/QS8.2.6a/14	Medical high-activity silicone oil purchase inspection specification
		JC/QS8.2.6b/01/06	Caps Injection Process Inspection Specification of Insulin coat
		JC/QS8.2.6b/01/11	Injection process inspection specification for insulin protective caps
		JC/QS8.2.6b/01/02	Specification for injection process inspection of core bar
		JC/QS8.2.6b/04/02	Inspection specification for assembly process of insulin syringe needle
		JC/QS8.2.6b/05/03	Inspection specification for assembly process of insulin syringe
		JC/QS8.2.6c/05	Finished product inspection specification of Disposable Insulin Syringe
		JC/QS8.2.6d/#	Test specification (performance test: physical)
		JC/WI7.6a/#	Instrument operating procedures
5	Packaging label specification	JC/QSP 7.5.11a	Product protection control procedure
		JC/QSP 7.5.11b	Label and packaging control procedure
		JC/QSP 7.5.8	Identification and traceability control

			procedure
		JC/DRWYDS-#	Packaging drawing
		JC/DRWYDS-#	Label drawing
6	Installation, maintenance, and service procedure and methods	JC/QSP 6.3b	Device management control procedure
		JC/QR6.3b/01	Equipment / mold configuration application form
		JC/QR6.3b/02	Equipment installation/acceptance record
		JC/QR6.3b/03	Production equipment list
		JC/QR6.3b/04	Tooling schedule
		JC/QR6.3b/05	Mold acceptance record
		JC/QR6.3b/06	Daily maintenance record of production equipment
		JC/QSP6.3b/07	Equipment regular maintenance and repair plan
		JC/QR6.3b/08	Equipment regular maintenance record
		JC/QR6.3b/09	Equipment / mold repair / commissioning record
		JC/QR6.3b/10	Equipment overhaul application form
		JC/QR6.3b/11	Device deactivation or retirement approval form
		JC/QR6.3b/12	Equipment accident report form
			Main equipment file
		JC/QSP 7.5.4	Service control procedure
		JC/QR7.5.4/01	Inquiry record
7	Risk management control and medical device instructions	--	Instruction Manual
		JC/QSP7.1b	Risk management control procedure
		JC/WI7.1b/06/01	Risk Management Report of Disposable Insulin syringes
8	other	JC/QR4.2.4/02	List of controlled documents
		JC/QR4.2.5/01	Record list

3.2.5 Labels on the package

- See Folder 2 # JC/QS9.7f-02-01 label for Disposable Insulin Syringes.

Chapter 4 GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

4.1 General safety and performance requirements

The device has fulfilled all applicable Essential safety and performance requirements per Annex I of Regulation (EU) 2017/745(MDR). Detailed information is given in the Folder 4 # JC/QS9.7f-04-01.

4.2 Applicable standards lists

(Harmonized standards, international standards, partly applicable standards)

Relevant standards applied to the device are listed as follows:

No.	Standards	Reference	Content
1.	MDR (EU) 2017/745	2017	Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2.	MEDDEV2.7.1	Rev4	Clinical Evaluation : A guide for manufacturers and notified bodies under directives
3.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
4.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
5.	EN 1041	2008+A1:2013	Information supplied by the manufacturer with medical devices
6.	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016)
7.	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
8.	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
9.	EN ISO 10993-4	2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
10.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
11.	EN ISO 10993-7	2008/AC:2009	Biological evaluation of medical devices —Part 7: Ethylene oxide sterilization residuals
12.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
13.	EN ISO 10993-11	2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
14.	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)

15.	EN ISO 10993-18	2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
16.	EN 62366-1	2015	Medical devices — Part 1: Application of usability engineering to medical devices
17.	EN ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purpose
18.	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 (ISO 11135:2014)
19.	EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
20.	EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
21.	EN ISO 11737-1	2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
22.	EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
23.	EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - General requirements
24.	EN ISO 11138-2	2017	Sterilization of health care products — Biological indicators Part 2: Biological indicators for ethylene oxide sterilization processes
25.	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments —Part 1: Classification of air cleanliness
26.	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 (ISO 14644-2:2015)
27.	EN 17141	2020	Cleanrooms and associated controlled environments - Biocontamination control
28.	ASTM F1980-16	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
29.	ASTM D4169-16	2019	Standard Practice for Performance Testing of Shipping Containers and Systems
30.	EN ISO 9626	2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
31.	EN ISO 80369-1	2018	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2018
32.	EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)
33.	EN ISO 8537	2016	Sterile single-use syringes, with or without needle, for

			insulin
34.	EN ISO 7864	2016	Sterile hypodermic needles for single use -- Requirements and test methods
35.	EN ISO 23908	2011	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Chapter 5 BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

Risk management is performed per EN ISO 14971:2019, and the Risk management plan and report is given as attachments

- ☒ Folder 5# JC/QS9.7f-05-01, Risk management plan
- ☒ Folder 5# JC/QS9.7f-05-02, Risk management report

Chapter 6 PRODUCT VERIFICATION AND VALIDATION

6.1 Pre-clinical and clinical data

6.1.1 Biocompatibility evaluation

Product biocompatibility was evaluated according to EN ISO 10993-1. Based on the test results of type examination report for Disposable Insulin Syringes issued by competent authority, it is concluded that the biocompatibility of the product is in line with essential safety and performance requirements from MDR.

☒ Folder 6# JC/QS9.7f-06-01 Product biocompatibility evaluation report.

☒ Folder 6# Biocompatibility Test Report

No.	Test description	Method	Test requirements	Report #	Conclusion
1	Cytotoxicity	EN ISO 10993-5:2009	No potential toxicity	SDWH-M201701238-1	Accord
2	Sensitization	EN ISO 10993-10:2010	No potential skin sensitization	SDWH-M201701238-2	Accord
3				SDWH-M201701238-5	Accord
4	Irritation or intracutaneus reactivity	EN ISO 10993-10:2010	No potential intracutaneous reactions	SDWH-M201701238-3	Accord
5	Acute Systemic toxicity	EN ISO 10993-11:2017	No potential acute system toxicity	SDWH-M201701238-4	Accord
6				SDWH-M201701238-6	Accord
7	Material mediated Pyrogenicity	EN ISO 10993-11:2017	No potential thermogenic reaction	SDWH-M201701238-8	Accord
8	In vitro hemolytic properties	EN ISO 10993-4:2017	nonhemolytic	SDWH-M201701238-7	Accord

6.1.2 Product performance test

The test of finished products concerning physical and chemical properties related to clinical application have been performed.

The type and self-test test reports of finished products are provided in Folder.

☒ Folder 6# Product Performance Test Report

No.	Report Name	Report No.
1	Type Test Report	2014QW6809
2	Self test report	JC/QR 8.2.6c/05

6.1.3 Usability evaluation

The hazards and hazardous situation related to the usability have been taken into consideration during risk management process, and the mitigation measures are documented in risk management file.

Usability engineering of the device is conducted according to EN 62366-1 and the result is documented in Usability Evaluation Report.

Refer to the following reports for the scenarios tested.

•Folder 6# JC/QS9.7f-06-02_Usability check list

•Folder 6# JC/QS9.7f-06-03_Usability evaluation report.

6.1.4 Packaging evaluation

Package description

The package is divided into three parts, primary package, middle package and external package. The primary package is blister sealing packaging or paper poly pouch consists of medical dialysis paper and PE plastic. Then the primary package is put into the middle packaging which made of paper cardboard. The external package is 5-layer corrugated fiberboard carton. The primary packaging is sealed packaging, and it shall be guaranteed that the product is sterile until opening.

Packaging material information

Primary packaging	Middle packaging	External packaging
Blister sealing packaging	Paper cardboard	5-layer corrugated fiberboard carton
Paper poly pouch		

Packaging list

Type of syringes	Model & specification	Content in packaging		
		Primary packaging	Middle packaging	Outer packaging
Type3	U-40, U-100	with a detached or detachable needle paper-plastic blister packaging or PE bag 1 piece/ per bag	Paper cardboard 100 pieces/ per box	5-layer corrugated fiberboard carton 2000piece/ per carton 3000piece/ per carton 3200 piece/ per carton
Type7	U-40, U-100	syringe with fixed needle tube paper-plastic blister packaging or PE bag 1 piece/ per bag		
Type8	U-40, U-100	syringe with fixed needle tube fitted		

		with protective end caps paper-plastic blister packaging or PE bag 10 piece/ per bag		

6.1.5 Sterile barrier system

The products are packaged in sterile barrier packaging system which aims to ensure the sterile condition of the products inside the packaging within specified shelf life. The primary package is paper-poly pouch/ blister sealing package by heat-sealing machine.

The primary packaging process is evaluated and validated according to EN ISO 11607-1/2. A validation group is established to coordinate and implement the validation, following the validation procedure.

Validation protocol has been established and implemented by the validation group. Validation report has been reviewed, approved and signed by the validation group. According to the validation result, routine operation and control work instruction for primary packaging has been established in work instruction.

The processes will be revalidated if changes are made to the equipment, product, packaging materials or packaging processes and etc., which compromise the original validation and affect the safety or efficacy of the products. Annual revalidation or reviews will also be performed and documented to evaluate the efficacy of the previous validation result.

The packaging form is sealed packaging, and it shall be guaranteed that the product is sterile until opening. The shelf life is 5 years after EO sterilization, the test results are meet the requirements of the EN ISO 11607-1/-2.

It is concluded that the sterile barrier packaging system performance of the product is in line with essential requirement from MDR and safe for the intended use.

The sterile barrier packaging system validation reports are given in Folder:

- Folder 6 # packaging sealing process validation report

6.1.6 Packaging Transportation evaluation

Stimulation tests are conducted based on evaluation of the factors impact on the packaging system according to ASTM D4169-16.

The test results showed that the Package transportation performance of the product is in line with essential requirement from MDR and safe for the intended use. If the Disposable Insulin Syringes adopt the different packaging material/process/equipment, it should be revalidated of the transportation evaluation.

- Folder 6 # Package transportation evaluation report

6.1.7 Product stability（Accelerated and real-time aging）

According to the standard of ASTM F1980-2016 Accelerated aging of sterile medical device packaging standard guidelines to do accelerated ageing test.

The company defined retention samples observation procedure, and take a regular observe and performance test for the samples. According to the test result, we could confirm the product has a stabilized performance in the service life.

Conclusion: The product meets the requirements after stability test. In order to ensure the safety and effectiveness of the product, the shelf life of the product is set to five years.

- Folder 6# SDWH-2013-20301 _Packaging verification (Accelerated Aging 5 years), Medical Dialysis Paper

6.1.8 Sterilization

The product is supplied sterile, and sterilized by EO sterilization to ensure SAL 10^{-6}.

The EO sterilization is conducted in-house. The sterilization process has been validated according to EN ISO 11135, which has thereby determined the routine control and monitoring parameters. Before sterilization, the bioburden of the device is verified by the manufacturer.

The validation and re-validation is conducted according to EO sterilization validation procedure, the protocol and result is documented in EO sterilization validation protocol and EO sterilization validation report.

- Folder 6 # EO sterilization validation report.

For routine release of sterilization, the sterilization certificate will be provided for each sterilization batch, reviewed and approved by Quality Department. The shelf life is 5 years after EO sterilization.

6.1.9 Clinical Evaluation

Since the evaluated products, Disposable Insulin Syringes are traditional low risk medical device and sold & used over decades, its Risk-Benefit-Evaluation is demonstrated through long time device using experiences.

The products' performance and safety is also guaranteed through specific design following relevant standards requirements, bench testing, and the implementation of quality management system.

For applied products, through the comprehensive clinical literature databases and post manufacturing experience, it is found that no new clinical risks are generated yet.

For example, Internet sides and homepages, and literature

a. http://www.ncbi.nlm.nih.gov/pubmed/ US National Library of Medicine National Institute of Health,

and/or

b. http://www.elsevier.com/wps/find/homepage.cws_home ELSEVIER

the Disposable Insulin Syringes, manufactured under the observed controlled conditions as described in intended use and the IFU, are safe in the field of healthcare personnel and no risk above the acceptable level are introduced by them.

Therefore, the Disposable Insulin Syringes are considered to be acceptable for Risk-Benefit-Evaluation since both effectiveness and safety are deemed to be acceptable.

Please refer to folder 6 # JC/QS9.7f-06-04 for Clinical Evaluation Plan and JC/QS9.7f-06-05 for Clinical Evaluation Report.

6.2 Additional information required in specific cases

a) The device not contains a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma in the first subparagraph of Article 1(8).

b) The device not contains is manufactured utilising tissues or cells of human or animal origin, or their derivatives.

c) The devices are not composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body.

d) The device not contains CMR or endocrine-disrupting substances in Regulation (EU) 2017/745 Section 10.4.1 of Annex I.

e) The device is placed on the market in a sterile condition, a description of the environmental conditions for the relevant manufacturing steps was provided in Chapter 3 DESIGN AND MANUFACTURING INFORMATION.

f) The device has measuring function, the scale on the barrel indicated the volume of insulin to be injected. The method used to ensure the accuracy of scale is established according to ISO 8537:2016;

g) The device is to be connected to other device(s) in order to operate as intended, a description of this Combination/configuration was provided in Chapter I DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSIRIES

Chapter 7 POST-MARKET SURVEILLANCE

Post-market surveillance is performed per MDR (EU) 2017/745 and MEDDEV 2.12 1/2, and the Post-market surveillance plan and report is given as attachments

- Folder 7 # JC/QS9.7f-07-01, PMS plan
- Folder 7 # JC/QS9.7f-07-02, PMCF plan