

HOLINX

Changzhou Holinx Industries Co., Ltd.

Add.: No. 1 Dongtang Road, Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China

<https://www.holinx.com/>

Document No.	HLX/ZS-1ml-001	Revision No.	A/0	Date of Revision	2022.02.01
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TECHNICAL DATASHEET OF STERILE HYPODERMIC SYRINGES FOR SINGLE USE



PRODUCT DETAILS											
Description:	Disposable Insulin Syringe 1ml, with needle 29GX1/2"										
Type:	Fixed needle										
Graduation:	0.02 ml										
Shelf life:	5 years from date of manufacturing										
REF No:	H100I29/12										
Composition:	<i>Disposable Insulin Syringe with needle is a medical device composed of:</i> <table><tr><td>-Barrel;</td><td>-Comes with the permanently attached needle; -Transparent cylinder allows easier and precise dosing, observation and elimination of air bubbles; -Clear and precise scale allows accurate and simple dosing; -Equipped with stopping design, which prevents the piston from accidentally leaves.</td></tr><tr><td>-Piston;</td><td>-Anatomically designed piston, which facilitates handling of the syringe. -Easy aspiration up to maximum volume.</td></tr><tr><td>-Gasket;</td><td>-Latex-free, with double ring; -Ensures good seal and high precision; -Allows a smooth and regular piston progress when in contact with high quality lubricant.</td></tr><tr><td>-Needle;</td><td>-Provides sharp and smooth puncture.</td></tr><tr><td>-Protective cap.</td><td>-Tight closure ensures high level of safety against accidental needle stick injury when handling the syringe.</td></tr></table>	-Barrel;	-Comes with the permanently attached needle; -Transparent cylinder allows easier and precise dosing, observation and elimination of air bubbles; -Clear and precise scale allows accurate and simple dosing; -Equipped with stopping design, which prevents the piston from accidentally leaves.	-Piston;	-Anatomically designed piston, which facilitates handling of the syringe. -Easy aspiration up to maximum volume.	-Gasket;	-Latex-free, with double ring; -Ensures good seal and high precision; -Allows a smooth and regular piston progress when in contact with high quality lubricant.	-Needle;	-Provides sharp and smooth puncture.	-Protective cap.	-Tight closure ensures high level of safety against accidental needle stick injury when handling the syringe.
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Materials: PP, Rubber (Latex Free), Stainless Steel, Lubricant

Sterilization: EO (Ethylene Oxide)

Product standards: ISO 7886-1:2017, ISO 7864-2016, ISO 8537

Certificates: CE, ISO 13485

Packaging: Single Blister packaging needle at side, 100pcs per box, 32boxes per carton

Intended Use:

Its purpose is to suck and introduce liquids. Not suitable for high pressures or cancer medicines.

Cautions:

- Read instructions before use.
- Before usage confirm the sterility validity, packing completeness, the LOT number and expiry date.
- Use only if package is undamaged and validity not expired;
- The syringes should be used immediately after unit package opened.
- To be used by qualified doctor or paramedic only.
- Check the tightness of needle before the use.
- For single use. The re-sterilization and/or use by more than one patient may cause a cross-infection.
- Destroy after use.

Instructions for use:

1. Select the appropriate syringe with hypodermic needle for your procedure.
2. Examine individual package for integrity of packaging prior to use. Do not use if packaging has been torn.
3. Before usage, open the unit package using aseptic technique.
4. Remove protective needle cap.
5. Draw up medication and administer injection using an aseptic technique in accordance with your facility's protocol.
6. Apply protective cap when procedure is finished.
7. Any used syringe is considered contaminated and should be disposed of in an approved container immediately after use.
8. To avoid risk of infection, immediately dispose of after single use.

Features:

- Non-toxic;
- Non-pyrogenic;
- PVC, PHT and DEHP free;



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- Latex free;
- Sterile unit packages.

Storage:

Keep away from sunlight. Protect from extreme humidity and heat sources. Not store with organic or chemical solvents. Not store with corrosive gases. Store in dry, cool, good ventilated and clean room, where the relative humidity is less than 80%.

Sample blister packaging design:

 Seringă de unică folosință	Precauție: • Nu reesterilizați • Steril dacă ambalajul nu a fost deschis sau deteriorat • Nu utilizați dacă ambalajul este deteriorat sau a fost deschis anterior • Aruncați după o singură utilizare • Nu depozitați la lumina directă a soarelui, la temperaturi extreme sau la umiditate ridicată	 ISO 13485 CE 0197 SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE) Add: Eiffelstrasse 80, 20537 Hamburg, Germany Changzhou Holinx Industries Co., Ltd. No. 1 Dongtang Rd., Zhenglu Town, Tianning District, Changzhou City, Jiangsu, China Repr. Aut. in Republica Moldova: S.C. IMAN Moldova Adr.: No 42, Gh. Asachi str., Chisinau, Republica Moldova	• Netoxic • Apirogen • De unică folosință • Fără latex	1 ML Insulină U-100 29GX1/2" REF: H160129-12 LOT: 20220815 PROD: 20220816 EXP: 20270815
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Editor:

Audit:

Approve:

