**HEZE YINUO MEDICAL INDUSTRY CO.,LTD**
**ADD.DINGTAO COUNTY, ECONOMIC DEVELOPMENT ZONE, HEZE CITY, SHANDONG, CHINA**
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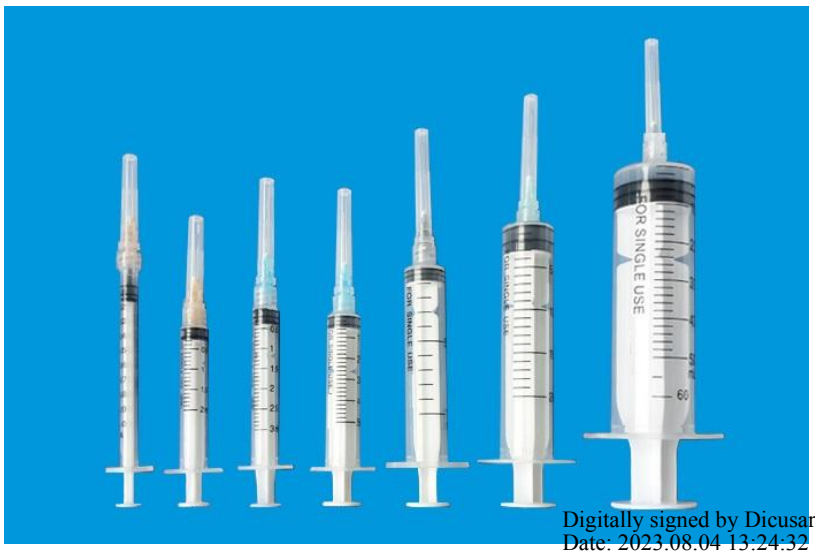
# TECHNICAL DATA SHEET

## STERILE HYPODERMIC SYRINGE FOR SINGLE USE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| | | |
|---|---|---|
| **1** | **General Information** | |
| 1.1. | Description: | Manufactured by Heze Yinuo Medical Industry Co.,Ltd<br>0.5ml,1ml,2ml, 2.5ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml,60ml,100ml<br>Sterile hypodermic syringe for single use.<br>Gasket in Latex or Latex free<br>Luer Slip or Luer Lock connector<br>Blister pacakge or Poly package |
| 1.2. | Used for: | The device is a syringe with or without needle, intend for clinical hypodermic, muscle, vein injection. |
| 1.3. | Advantages for user: | No air or liquid leakage with the perfect design.<br>Resistant to pressure.<br>User friendly ergonomic design.<br>Smooth sliding of plunger through barrel.<br>Uniform slipping of the syringe plunger.<br>Stopper to prevent piston from coming out of the syringe.<br>2-stage plunger sealing gasket that prevents the solution from returning during administration. |
| 1.4. | Warning: | Check the inner packaging carefully before use, do not use if find unwanted objects, package leakage, package broken or protective cover fall off.<br>Only use by trained medical staff.<br>Sterile valid is three years and please use in valid time. The valid time see the package.<br>Only for single use.<br>After using, pleas disposal it as conventional medical waste. |
| 1.5 | Store Conditions: | The products shall be stored in the indoors with relative humidity no more than 80%, no corrosive gas and well-ventilated. Also keep away from fluorine-containing disinfectant.<br>a) |
| 1.6. | Safety: | Phthalate Free.<br>Non-toxic.<br>Non-pyrogenic.<br>For Single Use Only.<br>Please check the usage information behind the blister pack and IFU provided. |
| 1.7. | How to Use: | Open the inner packaging and take off the product;<br>Tighten the needle;<br>Remove the protective cover;<br>Extract the drug liquid;<br>Exhaust the air and then inject. |
| **2** | **Design and Components** | |

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|---|---|---|
| 2.1. | Composed of: | 3 parts: Barrel, Plunger, Gasket (latex or latex free) |
| 2.2 | Raw Material | Barrel--Medical PP material<br>Plunger--Medical PP material<br>Piston-- Latex free<br>Needle tube---Medical 304 stainless steel<br>Needle hub---Medical PP material<br>Needle Seat---Medical ABS material<br>Needle cap---Medical PP material |
| 2.2. | Tip of the Barrel: | Luer slip, 6% conical Transparent.<br>Luer lock,6% conical Transparent |
| 2.3. | Volume Lines: | Numeric indication in each 1 ml;<br>lineation in each 0,2 ml printed with indelible ink.<br>Easy to read. |
| 2.4. | Package Details: | Blister Packing by medical grade paper and film suitable<br>or Poly package by medical grade PE for EO sterilization. Individually packed.<br>Box and Corrugated carton<br>Labelled and put required packing icons in accordance with EEC Directives and EN Standards. |
| 2.5. | Sterilization: | E.T.O. Gas |
| 2.6. | Shelf Life: | 5 years |
| **3** | **Complied Standards and Certificates** | |
| 3.1. | CE Marking | Yes |
| 3.2. | Conformity Assessment Route: | 93/42 / EEC Medical Device Directive<br>ISO7886, ISO7863, ISO13485 |
| 3.3. | Class | IIa,rule 6<br>Sterile Hypodermic Syringes for Single Use belongs to surgical invasive devices intended for transient use (less than 60 min) and is sterilized by EO. So according to MDD appendix IX classification rule 6, it is a class IIa medical device. |
| 3.4. | Other Certificates | ISO 13485 |
| 3.5. | UMDNS Code | 13-940 |
| **4** | **Hypodermic Needle List for the syringes with needle** | |
| 4.1 | Length and thickness in inches | |

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|---|---|
| 4.1.1 | 18G x 1 1/2" |
| 4.1.2 | 19G x 1 1/2" |
| 4.1.3 | 20G x 1 1/2" |
| 4.1.4 | 20G*1 1/4'' |
| 4.1.5 | 21G x 1 1/2" |
| 4.1.6 | 21G*1 1/4'' |
| 4.1.7 | 22G x 1 1/4" |
| 4.1.8 | 22G x 1 1/2" |
| 4.1.9 | 23G x 5/8" |
| 4.1.10 | 23G x 1" |
| 4.1.11 | 23G x 1 1/4" |
| 4.1.12 | 23G x 1 1/2" |
| 4.1.13 | 24G x 1" |
| 4.1.14 | 24G x 1 1/4" |
| 4.1.15 | 24G x 1 1/2" |
| 4.1.16 | 25Gx 5/8" |
| 4.1.17 | 25G x 1" |
| 4.1.18 | 25Gx1 1/2" |
| 4.1.19 | 26G x 1/2" |
| 4.1.20 | 27G x 1/2" |
| 4.1.21 | 27G x 1 1/2" |
| 4.1.22 | 29G x 1/2" |
| 4.1.23 | 29G*5/8'' |
| 4.1.24 | 29G*5/16'' |
| 4.1.25 | 30G x 5/16" |
| 4.1.26 | 30G x 1/2" |
| 4.1.27 | 31G x 5/16" |

| SIZE | | COLOR | | LENGTH OF REGULAR NEEDLES | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 13mm | 16mm | 19mm | 25mm | 32mm | 38mm |
| O.D (mm) | GUAGE | COLOR CODE | | 1/2" | 5/8" | 3/4" | 1" | 1 1/4" | 1 1/2" |
| 1.60 | 16G | | White | | | | | | |
| 1.20 | 18G | | Pink | | | | | | |
| 1.00 | 19G | | Beige | | | | | | |
| 0.90 | 20G | | Yellow | | | | | | |
| 0.80 | 21G | | Green | | | | | | |
| 0.70 | 22G | | Black | | | | | | |
| 0.60 | 23G | | Blue | | | | | | |
| 0.55 | 24G | | Purple | | | | | | |
| 0.50 | 25G | | Orange | | | | | | |
| 0.45 | 26G | | Brown | | | | | | |
| 0.40 | 27G | | Grey | | | | | | |
| 0.36 | 28G | | Blue-Green | | | | | | |
| 0.33 | 29G | | Red | | | | | | |
| 0.30 | 30G | | Light Yellow | | | | | | |

## 5 Performance Data

Performance tests are performed in accordance with ISO7886-1:2017 and ISO7864:2016.

5.1 **Physical requirement of syringe**

5.1.1 Extraneous matter
The surfaces of the syringe that come in contact with injection fluids during normal use shall be free from particles and

5.1.2 Lubricant:When the plunger stopper is fully inserted the amount of lubricant applied into the barrel shall not reach the Luer channel of the nozzle.

5.1.3 Tolerance on graduated capacity

| Nominal capacity of syringe V (ml) | Tolerance on anygraduated capacity | | Maximum dead space (ml) | Minimum overall length of scale to nominal capacity mark (mm) | Scale interval (ml) | Increment between graduation lines to be numbered (ml) | Forces for leakage testing | |
|---|---|---|---|---|---|---|---|---|
| | Less than half nominal capacity | Equal to or greater than half nominal capacity | | | | | Side force (±5 %) (N) | Axial pressure (gauge) (±5 %) (kPa) |
| V < 2 | ±(1,5 % of V + 2 % of expelled volume) | ± 5 % of expelled volume | 0.07 | 57 | 0.05 | 0.1 | 0.25 | 300 |
| 2 ≤ V < 5 | ±(1,5 % of V + 2 % of expelled volume) | ±5 % of expelled volume | 0.07 | 27 | 0.2 | 1 | 1.0 | 300 |
| 5 ≤ V < 10 | ±(1,5 % of V + 1 % of expelled volume) | ±4 % of expelled volume | 0.075 | 36 | 0.5 | 1 | 2.0 | 300 |
| 10 ≤ V < 20 | ±(1,5 % of V + 1 % of expelled volume) | ±4 % of expelled volume | 0.10 | 44 | 1.0 | 5 | 2.0 | 300 |
| 20 ≤ V < 30 | ±(1,5 % of V + 1 % of expelled volume) | ±4 % of expelled volume | 0.15 | 52 | 2.0 | 10 | 3.0 | 200 |
| 30 ≤ V < 50 | ±(1,5 % of V + 1 % of expelled volume) | ±4 % of expelled volume | 0.17 | 67 | 2.0 | 10 | 3.0 | 200 |
| V ≥ 50 | ±(1,5 % of V + 1 % of expelled volume) | ±4 % of expelled volume | 0.20 | 75 | 5.0 | 10 | 3.0 | 200 |

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| 5.1.4 | Graduated scale<br>1)The syringe shall have either only one scale or more than one identical scales, which shall be graduated and numbered at least at the intervals given in the table 4. The unit of volume shall be marked on the barrel.<br>2)The total graduated capacity may be equal to, or greater than, the nominal capacity. If the scale is extended beyond the nominal capacity, the extended portion shall be differentiated from the rest of the scale, such as:<br>a) encircling the scale number of the nominal capacity line;<br>b) using smaller scale numbers for the extra graduation lines;<br>c) using shorter graduation lines for the extra graduation lines;<br>d) using a broken line for the optional vertical line of the extra scale length.<br>3)Graduation lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.<br>4)Graduation lines shall be evenly spaced along the longitudinal axis between the zero graduation line and the line for the total graduated capacity.<br>5)When the syringe is held vertically, the ends of all graduation lines of similar length shall be vertically beneath each other. The lengths of the short graduation lines on each scale are recommended to be approximately half the length of the long lines<br>6.Overall length of scale to nominal capacity line |
| 5.1.5 | Barrel<br>1) Dimensions<br>Maximum capacity shall be determined by risk assessment with consideration of, for example, removal of air bubbles or risk of overdose.<br>2) Barrel flanges<br>The open end of the barrel shall be provided with barrel flanges. Barrel flanges shall be of adequate size, shape and strength for the intended purpose and shall enable the syringe to be held securely during use. The syringe design, such as barrel flanges, shall be such that the syringe will not roll more than 180° when it is placed on a flat surface at an angle of 10° to the horizontal. The barrel flanges shall be free from flash and sharp edges.<br>Plunger stopper/plunger assembly<br>When tested in accordance with Annex B of ISO 7886-1, the plunger stopper shall not become detached from the plunger. |
| 5.1.6 | Dead space<br>Dead space shall be minimized to reduce waste and transmission of infectious agents. |
| **5.2** | **Chemical requirement** |
| | Deoxidation substrate: KMnO4 consumable (0.002mol/L) difference between inspection fluid and control blank shall not more than 0.5ml.<br>Metal ion: 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.<br>pH: Exposure of distilled water to the finished syringe product shall not change its pH value by more than one unit.<br>EO residual: Resiual of each Infusion Set for Single Use shall not more than 10μg/g. |
| **5.3** | **Biological** |
| | Sterility: Shall be sterile.<br>Pyrogen: Shall be no pyrogen.<br>Biocompatibility<br>The biocompatibility shall comply with ISO10993 series standards. |

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**[Regular Symbols]:**

| | | | |
|---|---|---|---|
| | Manufacturer | | Consult instructions for use |
| EC REP | Authorised Representative in the European community | CE 0123 | CE mark and Identification number of Notified Body |
| | Caution | LOT | LOT No. |
| | Do not reuse | | Date of manufacture |
| STERILIZE | Dot not re-sterilize | | Validity |
| | Do not use if package is damaged | | Keep Dry |
| STERILE EO | Sterilized Using Ethylene Oxide | | Keep away from sunlight |
| LATEX | Contains of natural rubber latex | Use no hooks | Use no hooks |
| PHT DEHP | Contains of Phthalate | | upright in transportation |

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