**HEZE YINUO MEDICAL INDUSTRY CO.,LTD**
**ADD.DINGTAO COUNTY, ECONOMIC DEVELOPMENT ZONE, HEZE CITY, SHANDONG, CHINA**
**WWW.YINUOMEDPRODUCTS.COM**

# TECHNICAL DATA SHEET

# STERILE INFUSION SET FOR SINGLE USE

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| **1** | **General Information** | |
| 1.1. | Description: | Manufactured by Heze Yinuo Medical Industry Co.,Ltd<br>Sterile Infusion set for single Use<br>With Airvent, with filter, 1.5m PVC tube, PE roller clamp, with /without rubber sleeve<br>Luer Slip or Luer Lock connector<br>Blister pacakge or Poly package |
| 1.2. | Used for: | The combination of the device with product is infusion container.<br>The product is suitable for the use of human vein transfusion under the action of gravity. |
| 1.3. | Advantages for user: | No air or liquid leakage with the perfect design. Good Quality tube |
| 1.4 | Contraindications | 1.The product is made of PVC materials that containing DEHP. Clinical staff should pay attention to the adverse influence to high-risk groups (such as: newborn, pregnant and lactating women, kleinkinder and prepubertal male), try to use alternatives if can.<br>2.This product contains DEHP, so it is forbidden to infuse paclitaxel, fat emulsion and organic solvent containing ethanol.<br>3.This product is not suitable for infusion of fat soluble liquid such as fat emulsion.<br>4.This product has an adsorption effect on some drugs, such as nitroglycerin, nimodipine, amimonsulfone, taxol, cyclosporin A, and drugs which have known that are not suitable for the use of PVC infusion.<br>5.According to the research data domestic and abroad, clinical medical staff should pay attention to the interaction between PVC tube and transfusion drugs which may lead to the change of pharmacodynamics.<br>6.This product is prohibited for infusion of drugs that are incompatible with PVC.<br>7.This product is prohibited for high pressure infusion system and light sensitive liquid.<br>8.This product contains Latex, be careful if the patients are sensitive to the latex. |
| 1.5. | 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 5 years and please use in valid time. The valid time see the package.<br>Only for single use, discard it (cut) immediately after use.<br>After using, pleas disposal it as conventional medical waste. |
| 1.6 | Store Conditions: | Keep in the indoors with relative humidity no more than 80%,<br>No corrosive gas and well-ventilated.<br>Keep away from fluorine-containing disinfectant.<br>Store in clean,dry and insect free location. |

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| 1.7. | Safety: | Phthalate Free.<br>Non-toxic.<br>Non-pyrogenic.<br>For Single Use Only.<br>Please check the usage information behind the blister or poly pack and IFU provided. |
| 1.8. | How to Use: | 1. Check the PE package to ensure its in well status;<br>2. Open the PE package and take out the product;<br>3. Fix the infusion set, remove the spike cap and then insert it into infusion container.<br>If connect the product to the soft infusion bag, please turn off the air-vent cover ( default is on) .<br>4. Close the flow regulator, adjust the volume of liquid in the drip chamber, and then open the flow regulator to exhaust the air inside.<br>5. Remove the protective cover of needle and insert it into vein of the patient. Observe the<br><br>Note:blood return until it is in normal condition and then control the flow regulator to intended speed.<br>If need extra drug, inject it through injection site/injector.<br>Note: blood return tubing is only used to observe the blood return condition. It is prohibited to be used for puncture and drug adding. |
| **2** | **Design and Components** | |
| 2.1. | Composed of: | 1. Spike Cap,<br>2. Spike,<br>3. Air vent,<br>4. Chamber,<br>5. Filter, PVC tube,<br>6. Flow Regulator,<br>7. with or without Y site,<br>8. with or without rubber sleeve( Latex or Latex free),<br>9. Luer lock or Luer slip connector,<br>10. without or with Needle(Any size based on clinic need) |
| 2.2 | Raw Material | 1. Spike Cap--Medical PP<br>2. Spike---Medical ABS<br>3. Air vent---Medical PP<br>4. Chamber--Medical PVC<br>5. Filter--Medical PP/PES<br>6. Tube---Medical PVC<br>7. Flow regulator--Medical PE or ABS<br>8. Rubber Ball--Latex or latex free<br>9. Luer lock/Luer Slip--Medical ABS<br>10. Needle cap--Medical PP<br>11. Needle tube--Medical 304 stainless steel<br>12. Needle seat--Medical ABS |

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| 2.3. | Tip of the Barrel: | Luer slip, 6% conical Transparent.<br>Luer lock,6% conical Transparent |
| 2.4. | Drops | 20 drops/ml |
| 2.5. | Package Details: | Individually Blister Packing by medical grade paper and film suitable<br>or Individually Poly package by medical grade PE for EO sterilization.<br>Big Bag by medical grade PE<br>Corrugated carton<br>Labelled and put required packing icons in accordance with EEC Directives and EN Standards. |
| 2.6. | Sterilization: | E.O. Gas |
| 2.7. | 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>ISO13485, ISO8536, ISO7864 |
| 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 | 13-984 |
| **4** | **Hypodermic Needle List for the syringes with needle** | |
| 4.1 | Length and thickness in inches | |
| 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" | |

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| 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** | | |
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| | Item | requirement |
| **5.1** | **I Physical requirement** | |
| | particulate contamination | particulate contamination level≤90 |
| | Leakage | No leakage |
| | Connections between components | Any connections between fluid path components of the infusion set, excluding protective caps ,shall withstand a static tensile force of not less than 15N for 15s |
| | Closure-piercing(Spike) device | The closure-piercing device shall be capable of piercing and penetrating the closure of a fluid container without per-percing.No coring should occur during this procedure. |

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| | Air inlet device | The air filter shall be in compliance with the requirement of EN ISO 8536-4:2013/A1:2013 3.2 and 8.2.<br>The air inlet device shall be provided with an air filter to prevent the ingress of microorganisms into the container into which the device is to be inserted.<br>The air-inlet device shall be separate from or integral with the closure-piercing device.<br>When the air-inlet device is inserted into a rigid infusion container, the air admitted into the container shall not become entrained in the liquid outflow.<br>The air filter shall be fitted so that all air entering the rigid container passes through it and that the flow of fluid is not reduced by more than 20% of that from a freely ventilated container. |
| | Tubing | The tubing,made of flexible material,shall be transparent or transparent or sufficiently translucent so that the interface of air and water during the passage of air bubbles can be observed with normal or corrected vision.<br>The tubing,length distal to the drip chamber shall be not less than 1500 mm in lenth,including the injection site,when provided,and the male conical fitting |
| | Fluid filter | The infusion set shall be provided with a fluid filter;<br>when tested in accordance with EN ISO 8536-4:2013/A1:2013 Annex A.5,the retention of latex particles on the filter shall be not less than 80%. |
| | Drip chamber and drip tube | The drip chamber shall permit continuous observation of the fall of drops.<br>The liquid shall enter the drip chamber through a tube which projects into the chamber.<br>There shall be a distance of not less than 40mm between the end of the drip tube and the outlet of the chamber,or a distance of not less than 20mm between the drip tube and the fluid filter.The wall of the drip chamber shall not be closer than 5mm to the end of the drip tube.<br>The drip tube shall be such that 20 drops of distilled water or 60 drops distilled water at （23±2）℃ at a flow rate of (50±10) drops/min deliver a volume of (1±0.1)mL)or [(1±0.1)g.<br>The drip chamber should permit and facilitate the procedure of priming. |
| | Flow regulator | The flow regulator shall adjust the flow of the infusion solution between zero and the maximum.<br>The flow regulator should be capable of continuous use throughout an infusion without the tubing being damaged. There should be no deleterious reaction between the flow regulator and the tubing when stored in such a manner that there is contact. |
| | Flow rate of infusion fluid | The infusion set shall deliver not less than 1000ml of a sodium (mass concentration = 9g/l) in 10 min under a static head of 1m. |

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| | Injection site | When provided, the self-sealing injection sit shall reseal when tested in accordance with EN ISO 8536-4 and there shall be no leakage of more than one falling drop of water. The injection site should be located near the male conical fitting. |
| | Connector of luer slip/lock | The distal end of the tubing shall terminate in a male conical fitting in accordance with ISO594-2. |
| | protective cap | The protective cap at the end of the infusion set shall maintain the sterility of the closure-piercing device, the male conical fitting and the interior of the infusion set.<br>Protective caps should be secure but easily removable. |
| **5.2** | **Ⅱ Chemical requirement** | |
| | Reducing (oxidizable) matter | When tested under EN ISO 8536-4:2010/A1:2013 Annex B.2, the volume of Na2S2O3(c(Na2S2O3)=0.005mol/L) solution shall not exceed 2.0ml. |
| | EO, ECH residue | When tested in accordance with ISO 10993-7:2009, EO residue shall no exceed 4mg/device, ECH residue shall no exceed 9mg/device. |
| | Metal ions<br>（Ba, Cr, Cu, Pb, Sn）<br>Metal ions (Cd) | When tested in accordance with EN ISO 8536-4:2010/A1:2013 Annex B.3,<br>The extract shall not contain in total more than 1μg/ml of Ba, Cr, Cu, Sn and Pb, and not more than 0.1μg/ml of Cd. |
| | Titration acidity or alkalinity | When tested in acccordance with EN ISO 8536-4:2013 /A1:2013Annex B.4, not more than 1ml of either standard volumetric solution shall be required for the indicator to change to the colour grey. |
| | UV absorption of extract solution | When tested in accordance with EN ISO 8536-4:2010/A1:2013 B.6, the extract solution S1 shall not show absorption greater than 0.1. |
| | Residue on evaporation | When tested in accordance with EN ISO 8536-4:2010/A1:2013 Annex B.5, the total amount of dry residue shall not exceed 5mg. |
| **5.3** | **Ⅲ Biological** | |
| | Sterility | Shall be sterile. |
| | Pyrogenicity | The infusion set and/or the air-inlet device shall be assessed for freedom from pyrogens by using a suitable test, and the results shall indicate that the infusion set is free from pyrogens. |
| | Haemolysis | The infusion set shall be assessed for freedom from haemolytic constituents and the result shall indicate that the infusion set is free from haemolytic reactions. |
| | Toxicity | Materials shall be assessed for toxicity by carrying out suitable tests, and the results of the tests shall indicate freedom from toxicity. |

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**[Regular Symbols]:**

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| | 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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