

Zibo Eastmed Healthcare Products Co., Ltd.

Address: No.118 , Huaguang Road, Zhangdian District, Zibo City, Shandong Province, China

ANALYSIS CERTIFICATE

| Item Name | Disposable 1ml / cc Luer Slip syringes | Needle Size | 27GX 1/2" |
|--|--|----------------------------------|------------------------------|
| Lot No. | 20221116 | Lot Qty | 198000pcs |
| MFG DATE | 20221116 | Inspection Item | Biological/Chemical/Physical |
| EXP DATE | 20271115 | Inspection Date | 2022.12.10 |
| Standards | ISO8537/YY0497 | Report Date | 2022.12.15 |
| Date of elaboration: | 2022.12.15 | Expiration date | 2027.11.15 |
| Item | Requirements | Result | Conclusion |
| Biological | | | |
| Sterility | Shall be sterility,no bacteria | Sterile | Pass |
| Pyrogenicity | Shall be non-pyrogenicity | Non-pyrogenicity | Pass |
| Chemical | | | |
| Limits for acidity or alkalinity | the difference of PH value should be no more than 1 | 0.18 | Pass |
| Limits for extractable metals | the color of the inspection solution should not be deeper than the color of the blank reference solution | Conforms | Pass |
| Physical | | | |
| Tolerance on graduate capacity | Shall be conform the requirement | Conforms | Pass |
| Freedom from extraneous matter | Shall be clean and free from extraneous matter when viewed by normal or corrected vision without magnification | Conforms | Pass |
| Graduated lines | Shall be conform the requirement | Conforms | Pass |
| Piston/plunger assembly | Shall be conform the requirement | Conforms | Pass |
| Lubricant | Shall not be visible droplets or particles under normal or corrected-to-normal | Conforms | Pass |
| Dead space | Shall be conform the requirement | 0.0025~0.0039ml | Pass |
| Needle point | Shall appear sharp,no burrs and hooks | Conforms | Pass |
| Bond between hub and and needle tube | Shall not be broken by the <u>22</u> N force | Conforms | Pass |
| Needle Point puncture pressure | Not more than <u>0.7</u> N | Conforms | Pass |
| Needle tube size | Shall be conform requirement | Length: 11~14m | 11.93~13.09mm |
| | | External diameter: 0.335~0.345mm | 0.337~0.340mm |
| Needle tube bore | Shall be clean;no dirt through the tube bore | Conforms | Pass |
| Connect effect between needle hub and tube | Shall be straightness,no deflection clearly | Conforms | Pass |
| Conclusion | PASS | | |

Examiner: Liu Fang

Checker: Li Gang

