

Zibo Eastmed Healthcare Products Co., Ltd.

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

ANALYSIS CERTIFICATE

Item Name	Disposable 20ml / cc Luer Lock syringes	Needle Size	21GX 1 1/2"
Lot No.	20210826	Lot Qty	90400pcs
MFG DATE	20210826	Inspection Item	Biological/Chemical/Physical
EXP DATE	20260825	Inspection Date	2021.09.10
Standards	ISO8537/YY0497	Report Date	2021.09.15
Date of elaboration:	2021.8.26	Expiration date	2026.03.25
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		