

Zibo Eastmed Healthcare Products Co., Ltd.

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

ANALYSIS CERTIFICATE

Item Name	Disposable 10ml / cc Luer Lock syringes	Needle Size	21GX 1 1/2"	
Lot No.	20220426	Lot Qty	384000pcs	
MFG DATE	20220426	Inspection Item	Biological/Chemical/Physical	
EXP DATE	20270425	Inspection Date	2022.07.10	
Standards	ISO8537/YY0497	Report Date	2022.07.15	
Date of elaboration:	2022.07.15	Expiration date	2027.04.25	
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: 11~14mm	11.93~13.09mm	Pass
		External diameter: 0.335~0.345mm	0.337~0.340mm	Pass
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				

Examiner: Liu Fang

Checker: Li Gang

