

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 ½ ”
Lot No.	20221116		Lot Qty	225000pcs
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	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	PASS			

Examiner: Liu Fang

Checker: Li Gang

