

ZIBO EASTMED HEALTHCARE PRODUCTS CO LTD

ANALYSIS CERTIFICATE

Product Name	Infusion set	Sterile Date	2022.1225
Lot No.	20221106	Lot QTY.	100000pcs
MFG DATE	20221106	EXP DATE	20271105
Test Basis	ISO8536-4:2012	Report Date	202212.25
Test Items	Requirements		Result
Particles contamination	The number of particles shall be not exceed the contamination index.(≤ 90)		33-38
Sealing function	It shall no signs of air leakage.		conformity
Linkage strength	The linkage can endure $\geq 15N$ steady pull for 15s		conformity
Close-piercing device	It shall be capable of piercing and penetrating the closer of a fluid container without pre-piercing.no coring should occur this procedure.		conformity
Dimensions of the Close-piercing device	L=28 \pm 1mm		28.28—28.34
	Big carry: 5.6 \pm 0.1 mm		5.54-5.58
	Small carry: 5.2 $^{+0.1}_{-0.2}$ mm		5.18-5.22
tubing	It should be Transparent or sufficiently Transparent		conformity
	Length ≥ 1600 mm		1950-1960
	Tube Length ≥ 1250 mm		1815-1825
	Thickness of wall ≥ 0.4 mm, Outer diameter ≥ 3.5 mm.		0.55 4.1
filter	Filtration rate is not less than 80%		92%
Air-inlet device	The air-inlet device shall be provided with a protective cap over the Close-piercing device or needle		-----
	The Air-inlet device shall be provided with an air filter		-----
	The Air-inlet device shall be separate from,or integral with,the closure-piercing device		-----
	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.		-----
	The fluid is not reduced by more than 20%		----
Reducing(oxidizable)matter	The total amount of potassium permanganate solution used[c(KmnO ₄ =0.002mol/L)] shall not exceed 2.0ml		0.62
Titration acidity or alkalinity	Not more than 1ml of either standard volumetric solution shall be required For the indicator to change to the colour grey		0.4
UV absorbency	Absorbency of inspection solution should not exceed 0.1.		0.04
EO residue	EO residua of each set of Transfusion system should not be more than 10 μ g/g.		conformity
Sterility	It should be sterile.		conformity
Pyrogen	There should be no pyrogen.		conformity
Conclusion:		conformity	
Examiner:	Liu Fang	Checker:	Li Gang

