

MEDTRUE ENTERPRISE CO.,LTD

Certificate of Analysis

Report No.: 2006206

Description	Infusion Set with Burette	Type	150ml	Lot No.	20231026	Quantity	53000PCs
Sterilization Date	2024.03	Sample Selection Date	22024.03	Sample Quantity		53000PCs	
Executive Standard	ISO8536-5:2004	Mfg. date	2023.10.26	Exp. date		2028.10.26	
Inspection Items	Standard Stipulations						Inspection Results
Biological Performance							
Sterilization	Sterile						Pass
Pyrogen	Pyrogen-free						Pass
Chemical Performance							
Reducing Material	0.005mol/L Sodium thiosulfate Consumption Difference ≤2.0mL						0.42ml Pass
Titration acidity or alkalinity	Volume of required sodium hydroxide standard solution or hydrochloric acid standard solution≤1ml						0.38ml Pass
Ultraviolet Absorption	≤0.1						0.023 Pass
Residue on Evaporation	The total amount of dry residue shall not exceed 5 mg						3mg Pass
EO Remnants	No more than 0.5mg for each set						0.12mg Pass
Physical Performance							
Particulate contamination	Contamination index limit N≤90						Pass
Leakage test	Immerse the set with one end blocked in water at (40±1)℃ and apply pressure of 20KPa for 15s; fill the set with degassed, distilled water, subject it to an internal excess pressure of -20KPa at (40±1)℃ for 15s, air leakage shall not be observed.						Pass
Tensile strength	Connection between components, protective jacket excluded, should be able to withstand a static force of not less than 15N for 15s.						Pass
Closure-piercing device	Pierce and penetrate closure of a fluid container without pre-piercing, no coring should occur.						Pass
Air Filter	Air filter rate ≥90%,Flow reduction by air filter<20%						97% 6.4% Pass
Soft Tube	Tube should be transparent or sufficiently translucent, when bubbles pass by, normal or corrected eyesight is able to observe air and water interface.						Pass
Liquid Filter Rate	Liquid filter rate≥80%						98% Pass
Volume Tolerance	Tolerance on capacity greater than half of nominal capacity should be ± 4% of expelled volume.						-1.3% Pass
Flow Regulator	Flow regulator can be used without damaging the tube during an infusion, and no deleterious reactions occur when stored with tube.						Pass
Flow Rate	Under 1m static head, for 20 drops/ml drip chamber, the infusion set shall deliver not less than 1000ml of sodium chloride solution (ρ=9g/L) within 10min; for 60 drops/ml drip chamber, the infusion set shall deliver not less than 1000ml of sodium chloride solution within 40min.						>1200ml/40min Pass
Conclusion: It complies with the stipulations of ISO8536-5:2004 standard.							
				Seal:			
Remarks: Without needle.							

Inspected by:

Checked by:

Verified by:

Report Date: 2024.3.30

