

Certificate of Analysis

1. Commodity	Accufuser		
2. Model No.	C2000M		
3. Lot No.	1B5E050		
4. Manufactured Date	2025-05-21		
5. Sterilization Date	2025-05-22	Batch No.	생-멸 EA13
6. Issue Date	2025-06-09		

Item		Limits		Results	Decision	Relevant SOP' s
Physical Test	Appearance	No Defect		No Defect	Pass	WYM-I090-P03
	Flow rate	3.33ml/min	±10%	-5.71%	Pass	WYM-I090-05
	Basal/Bolus Function					WYM-I090-06
	Tubing	No cutting after applying 15N for 15 sec.		Normal	Pass	WYM-I090-07
	Resistance to pressure	150N for 5 sec.		Normal	Pass	WYM-I090-07
	Drop test	No leakage		Normal	Pass	WYM-I090-07
	Water-tightness	No leakage		Normal	Pass	WYM-I090-07
	Adhesion Strength	Over 2.0kgf		Normal	Pass	WYM-I090-04
Biological Test	Acute Systemic Toxicity	No Defect within 7days		MTK-008984	Pass	K.P General Test
	Pyrogen	LAL reagent		MTK-008984	Pass	
Chemical Test	Appearance	Colorless, Transparent		MTK-008984	Pass	
	pH	NMT 1.5		MTK-008984	Pass	
	KMnO ₄ Reducing Substances	NMT 2.0ml		MTK-008984	Pass	
	Heavy Metals	The sample solution should not be darker than the control solution		MTK-008984	Pass	
	Residue on Evaporation	NMT 1.0mg		MTK-008984	Pass	
Sterility Test	Biological Indicator	Negative Growth within 2days		Negative	Pass	WYM-I090-02
	Chemical Indicator	Color Change		Change	Pass	
	Sterility	Negative Growth within 14days		Bacteria	Pass	
				Fungi	Pass	

Issued by
Q.A Manager

S. W. Park Ah