

Certificate of Analysis

1. Commodity		Accufuser				
2. Model No.		C0040M				
3. Lot No.		1B1K18				
4. Manufactured Date		2021-11-02				
5. Sterilization Date		2021-11-04		Batch No.	생-멸 KE05	
6. Issue Date		2021-11-18				
Item		Limits		Results	Decision	Relevant SOP' s
Physical Test	Appearance	No Defect		No Defect	Pass	WYM-I090-P03
	Flow rate	4.0ml/hr	±10%	5.00%	Pass	WYM-I090-05
	Basal/Bolus Function					WYM-I090-06
	Air Tightness	No Bubble Appearance		Normal	Pass	WYM-I090-07
	Adhesion Strength	Over 2.0kgf		Pass	Pass	WYM-I090-04
Biological Test	Acute Systemic Toxicity	No Defect within 7days		MTK-008984	Pass	ISO10993-11
	Pyrogen	LAL reagent		-Reaction	Pass	WYM-I090-08
Chemical Test	Appearance	Colorless, Transparent		MTK-008984	Pass	K.P General Test
	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 7days		Negative	Pass	WYM-I090-02
	Chemical Indicator	Color Change		Change	Pass	

Issued by
Q.A Manager

K. M. Seong 