

Certificate of Analysis

1. Commodity		Accufuser				
2. Model No.		C0100L				
3. Lot No.		1B0A186				
4. Manufactured Date		2020-01-31				
5. Sterilization Date		2020-02-04		Batch No.	생멸 BF02	
6. Issue Date		2020-02-18				
Item		Limits		Results	Decision	Relevant SOP' s
Physical Test	Appearance	No Defect		No Defect	Pass	WYM-I090-P03
	Flow rate	10.0ml/hr	±10%	-1.60%	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		Normal	Pass	WYM-I090-10
	pH	NMT 1.5		0.13	Pass	
	KMnO ₄ Reducing Substances	NMT 2.0ml		0.40	Pass	
	Heavy Metals	The sample solution should not be darker than the control solution		MTK-008984	Pass	K.P General Test
	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

C. H. Kim 