

Certificate of Analysis

1. Commodity		Accufuser & Accufuser Plus				
2. Model No.		C2000M				
3. Lot No.		AKHKJ96				
4. Manufactured Date		2016-11-15				
5. Sterilization Date		2016-11-16	Bacth No	생-멸KJ16		
6. Issue Date		2016-12-02				
Item		Limits		Results	Decision	Relevant SOP' s
Physical Test	Appearance	No Defect		No Defect	Pass	WYM-090-03
	Flow rate	200ml/hr	±10%	-7.47%	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/mm ²		Pass	Pass	WYM-I090-04
Biological Test	Acute Systemic Toxicity	No Defect within 7days		MTK-004825	Pass	ISO10993-11
	Pyrogen	LAL reagent (consist of Endotoxin 0.25 EU/ml)		-Reaction	Pass	WYM-I090-08
Chemical Test	Appearance	Colorless, Transparent		Normal	Pass	WYM-I090-10
	pH	NMT 2.0		0.12	Pass	
	KMnO ₄ Reducing Substances	NMT 2.0ml		0.60	Pass	
	Heavy Metals	NMT 2.0ppm		MTK-004958	Pass	K.P General Test
	Residue on Evaporation	NMT 1.0mg		MTK-004958	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 