

Appendix 2

Request	Registered Item for change	Manufacturer of Domestic Medical Devices			Manufacturer of Imported Medical Devices				
		Name of the manufacturer		Address of the manufacturer	Management representative	Name of the manufacturer	Address of the manufacturer	The domestic medical device firm	
		Involving a transfer of ownership	Name					Involving a transfer of agent rights	Name
	A photocopy of Manufacturing license	O	O	O	O	O	O	O	O
	A photocopy of the medical device business permit	O	O					O	O
	Evidentiary documents issued by the household/business registration agency or related official agency of the country where the manufacturer is located			O			O		
	Evidentiary document showing appointment of the management representative				O				
	The original letter of declaration for change from the manufacturer					O	O		
	The original certificate issued by the highest health authority in the country where the manufacturer is located					O			
	The original agreement issued by the medical device firm for transfer of Manufacturing license	O						O	
	The original letter of authorization from the manufacturer ¹							O	

Declaration of consistency on QMS	O							
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Note:

1. Should clearly state that the terminated and the subsequent authorization and registration of medical device firms; the matters authorized and the addresses of the terminated and subsequent medical device firms shall be included, with a period of validity of 1 year.