

## Appendix 2

Registered Item for change  Request	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A photocopy of the medical device business permit	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/>	<input type="checkbox"/>
Evidentiary documents issued by the household/business registration agency or related official agency of the country where the manufacturer is located			<input type="checkbox"/>			<input type="checkbox"/>		
Evidentiary document showing appointment of the management representative				<input type="checkbox"/>				
The original letter of declaration for change from the manufacturer					<input type="checkbox"/>	<input type="checkbox"/>		
The original certificate issued by the highest health authority in the country where the manufacturer is located					<input type="checkbox"/>			
The original agreement issued by the medical device firm for transfer of Manufacturing license	<input type="checkbox"/>						<input type="checkbox"/>	
The original letter of authorization from the manufacturer <sup>1</sup>							<input type="checkbox"/>	

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.