



Authorized Representative Registration Variation / Renewal Form

- Authorized Representative Name: -----
- Registration Certificate No. ----- Mobile No: -----
- Contact Email: -----

(1) Adding New Scope Of Service	
New Scope	
Medical Devices Name	
Storage	<input type="checkbox"/> Same Existing Store <input type="checkbox"/> Require New Store
Manufacturer Name	
Authorization Letter	<u>Attach</u>

(if more than one scope, please attach list) / For Selecting scopes, please refer to the list of scopes in Authorized Representative Registration Guideline.

(2) Removing Scope Of Service	
Scope	
Medical Devices Name	
Manufacturer Name	
New supplier Name	
Termination Letter	<u>Attach</u>
List of previously supplied medical devices (end users)	<u>Attach</u>
Authorization Letter	<u>Attach</u>

(3) Changing Address							
Old Address	Area		Flat No.		Building		Road No.
New Address	Area		Flat No.		Building		Road No.
Old CR Copy	<u>Attach</u>						
Capture of initial approval on Sijilat	<u>Attach</u>						
Inspection Request Form	<u>Attach</u>						



(4) New Storage

Storage Type	<input type="checkbox"/> Outside Main Office. <input type="checkbox"/> Outsourced.				
Storage Address	Area		Building		Road No.
Storage Record Capture	<u>Attach</u>				
CR Copy in case of outsourced	<u>Attach</u>				
Inspection request form	<u>Attach</u>				
Engineering Drawing (Receiving area, Dispatch area, quarantine area....)	<u>Attach</u>				

For each type of variations, NHRA may ask for additional Requirements

(5) Renewal of Registration Certificate

Any changes to the previously submitted details?	<input type="checkbox"/> Yes, if so please fill in the variation form. <input type="checkbox"/> No
<p><u>Please provide updates or updated version (with a minimum validity of one year) of the following document:</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> List of employees for medical devices and their qualification. <input type="checkbox"/> List of manufacturers distribution authorization letter or contracts. <input type="checkbox"/> Quality management system (QMS), if any. <input type="checkbox"/> Commercial Registration CR. <input type="checkbox"/> List of service contracts being provided to local Healthcare Facilities licensed by NHRA with the validity period. <input type="checkbox"/> Policies <input type="checkbox"/> List of recalls and adverse events from the previous license date of issuance including each case final report. <input type="checkbox"/> List of locally discarded items including all the following information - Product name, manufacturer name, Country of origin, batch number, serial number, quantity, reason, discarding evidence. <input type="checkbox"/> List of returned items to the manufacturer including all the following information - Product name, manufacturer name, Country of origin, batch number, serial number, quantity, reason, return evidence. <input type="checkbox"/> List of supplied medical devices to Health Care Facilities as per the Permit to Use guideline. 	



NHRA Comments for Registration Certificate Renewal

For NHRA use only

Violations			
<input type="checkbox"/> Violations Records			
<input type="checkbox"/> N/A			
Violation	Type	No.	N/A
	Importation		<input type="checkbox"/>
	Registration		<input type="checkbox"/>
	Marketing		<input type="checkbox"/>
	Post Market Surveillance		<input type="checkbox"/>
	Storage		<input type="checkbox"/>
	Transportation		<input type="checkbox"/>
Medical Devices Registration			
No. of submitted Applications Last year			
Renewal Request Status			
<input type="checkbox"/> Approved			
<input type="checkbox"/> Rejected			
NHRA Comments	----- ----- ----- ----- -----		