FAQ

No	Question	Answer
1.	How to apply for re-registration?	Please apply through the MeDC@St application system. The re-registration button will appear within 1 year prior to expiry date. Please notify through helpdesk in the application system if the button is still cannot be found within the 1 year of expiry.
2.	For conformity assessment by CAB, do we have to contact same CAB?	Registration holder may choose same CAB as previously engaged with or different CAB to do the conformity assessment for re-registration.
3.	If I don't have any changes from previous registration, do we still need to submit change notification?	No, you do not have to submit change notification if there's no change notification as per guidance document MDA/GD/0020 Change Notification for Registered Medical Device. Please provide declaration that there is no change on the device.
4.	For medical device-drug combination products, do we have to wait for the endorsement letter before we proceed with the re-registration?	You may use the acknowledgement letter until further notify by MDA. Please check for announcement on the MDA portal from time to time.
5.	Post market surveillance. Do we need to declare on mandatory problem reporting as well? or just declare on Field Corrective Action (FCA) /recall?	Please declare for mandatory problem reporting, FCA and recall. Please state date of last audit.
6.	What is the Turn Around Time for approval re-registration?	Same as current registration, the turnaround time is as below: Class A – 30 days Class B, C and D – 60 days
7.	Can you clarify the criteria for correct label?	Please refer to guidance document on labelling. MDA/GD/0026 Requirements for Labelling of Medical Devices. Please check for announcement on the MDA portal from time to time.
8.	Change to the list of configurations (loc). If the changes only decided when we preparing for renewal. does it mean we have to submit the change notification first then only proceed for renewal?	Yes, please submit for change notification before applying the re-registration.
9.	If some of the items in the list of configurations are about to be	No, you are required to apply for change notification for the removal of devices.

	discontinued by the manufacturer, can we remove them in this re-registration?	
10.	If there is change in classification during re-registration, will the certification number remained same or we have to submit a new application?	If the classification of the registered medical device changed, applicant is required to submit as new registration application.
11.	Is the registration number remain the same if applied for re-registration?	Yes, the medical device registration number will remain same if apply for re-registration.
12.	If CE certificate has expired or no longer available, can we still apply for re-registration.	You have to apply for change notification if there is removal of pre-market approval or CE certification. You may continue with re-registration after approval change notification of the removal of the certification.
13.	How is CAB to conduct conformity assessment for re-registration?	CAB has to conduct conformity assessment via verification route for re-registration of registered medical device.