Fee Structure for Licensing of Establishment

New & Renewal Application

As specified in the Fifth Schedule of the Medical Device Regulation 2012, the application and licensing fee for both new license and renewal license application are imposed as follows:

Establishment	New Application		Renewal Application	
role	Application	License Fee	Application	License Fee
	Fee (RM)	(RM)	Fee (RM)	(RM)
Manufacturer	250	4,000	200	2,000
Authorised	250	4,000	200	2,000
Representative				
Distributor	250	2,000	200	1,000
Importer	250	2.000	200	1,000

For further information, please refer to Fifth Schedule of Medical Device Regulations 2012.

Change of ownership for medical device registration

Service / processing fee (**RM 500.00**) imposed per medical device registration ID, towards the new Authorised Representative upon completion of change of ownership for medical device registration.

(Refer MDA/GD/0041, Change of Ownership for Medical Device Registration)