

All submission of notification of changes shall be accompanied with a fee as per the table below. Payment shall be made by the applicant prior to endorsement/acknowledgement by MDA.

Table 1: Change notification fees

Medical Device Risk Class	Category 2 (RM)	Category 3 (RM)
Class A	50	30
Class B	500	
Class C	1000	
Class D	1500	
<i>Medical device that contains a medicinal product</i>	2500	

Table 2: Example of calculation fees for change notification of single and multiple applications

No	Application	Calculation
1	Single application for one category (either Category 2 or Category 3)	Example: The applicant has submitted a single application under Category 2, Class B. <i>Calculation fee = fee for Category 2 and Class B</i> <i>= RM 500</i>
2	Single application for Category 2 and Category 3	Example: The applicant has submitted single application under Category 2, Class B and Category 3, Class B <i>Calculation fee = fee for Category 2, Class B</i> <i>+ fee for Category 3, Class B</i> <i>= RM 500 + RM 30 = RM 530</i>
3	Multiple application for one category (either Category 2 or Category 3)	Example: The applicant has combined 3 submission IDs under Category 2, Class B. <i>Calculation fee = number of submission ID x fee for Category 2</i> <i>= 3 x RM 500</i> <i>= RM 1500</i>
4	Multiple application for Category 2 and Category 3	Example: The applicant has combined 3 submission IDs under Category 2, Class B and Category 3, Class B <i>Calculation fee = (number of submission ID x fee for Category 2) + (number of submission ID x fee for Category 3)</i> <i>= (3 x RM 500) + (3 x RM 30)</i> <i>= RM 1500 + RM 90</i> <i>= RM1590</i>