

Elevation Fees of Medical Device Marketing Authorization (MDMA)

New Applications (Based on Risk Classification for Medical Devices)			
Fee Group	Risk Classification	Lead Time	Elevation Fee
FG (1)	Class A	35 - 60 Working Days (Based on Product type, risk classification and number of products included within the application)	15,000 SAR
FG (2)	Class B		19,000 SAR
FG (3)	Class C		21,000 SAR
FG (4)	Class D		23,000 SAR
Update and Renew Applications			
Type of Change Request		Fee Type	Elevation Fee
Renew		Reduced	5,000 SAR
Add device(s)			
Add model(s)			
Change brand name			
Update technical file of device(s)			
Transition period letter			
Minor change in manufacturer name/address			
Update label(s) only		Administrative	1,100 SAR
Update IFU(s) only			
Update advertising materials only			
Change risk classification		Full	Full fee according to risk classification
Change legal manufacturer name/address			

For inquiries, please contact the Registration Support Team at MD.RS@sfda.gov.sa