

Announces..

The update of Medical Device Marketing Authorization (MDMA) Evaluation Fees

These updated fees will be effective starting from Sunday February 28, 2016
All MDMA applications submitted before that date will be subjected to old MDMA fees.

Medical Device Marketing Authorization Evaluation Fees Table

Fee Groups	The Basis of the application for SFDA Marketing Authorization	Evaluation Fee	Lead Time (Working Day)
FG (1)	All Class I	SR 15000	35
	General IVD (Other)/ Exempt IVD (TGA)		
FG (2)	All Class II / Class IIa	SR 19000	35
	Self-test IVD / Listable IVD		
FG (3)	Class IIb / Class III (CA,PAL)	SR 21000	35
	Annex II List B (IVD)		
FG (4)	All other class III /class IV /AIMD	SR 23000	35
	Annex II List A (IVD)/ Registrable IVD		

- For class I non- sterile/ non-measuring, MDMA Validity will be 3 years.
- For all other classes, MDMA will be valid for the remaining validity of the original license or 3 years for undefined license validity.

For any inquiry, please contact MDMA team
Tel.: 011 2038222 Ext. 3905