

<<Medical Device(Class II) :Certification>>

		Fee (tax excluded)	Note
Pre-Application	Checking classification of product (Class II)	JPY50,000 per item	*Check classification, Japanese Accepted Names (JMDN), Certification standards, Basic requirement standards and Japanese Industrial Standards. *Inquiry to registered certification body
	Support for pre-application consultation by PMDA (*if needed)	JPY50,000 per time	*Consultation fee will be paid to PMDA separately (actual cost and expenses:JPY39,400 per time) *May be needed several times depends on the case.
Application	Support for application of registration of foreign manufacturer	JPY150,000 per application	*Fee for application will be paid to PMDA separately(actual cost and expenses:JPY90,000 per request). *No need if you have original copy of registration certificate.
	Arrangement of standard test by inspection body	Actual costs and expenses	
	Support for application for certification of item	(1) Phase I - JPY500,000 (2) Phase II - JPY250,000 (3) Phase III- JPY250,000 Total JPY1,000,000- per item + fee of compliance review	* Fee of application for certification will be paid to registered certification body separately. The fee depends on registered certification body.
	Notification of succession of marketing certification of medical device	Request to partner company (it will be quoted separately)	
	Notification of minor change of medical device/Application for partial changes	Request to partner company (it will be quoted separately)	
Importing/Post-marketing	Entrustment fee of medical device	1st year : JPY600,000 From 2nd year on : JPY300,000	*In case of succession of marketing certification of medical device, it will be discussed separately.
	Handling fee (product labelling, customs clearance, quality control)	Basic:JPY20,000 per item/month	*Depending on requested work, additional fee may apply.
	Handling fee for market release	5% of cost price based on invoice *May be negotiable during contract renewal depending on annual amount of import	

※Regarding expenses such as warehouse operation fee, storage fee, transportation fee, customs clearance fee and import consumption tax, actual costs and expenses will be charged.

※Regarding expenses such as safety management after market release and recall will be charged separately.