

<<Medical Device(Class I):Notification>>

Medilex Co., Ltd. 6F Ogura billding 8-18-11 Ginza, Chuo-ku, Tokyo, Japan TEL: +81-3-6264-2615 FAX: +81-3-4586-7032 E-mail: info@medilex.co.jp

1			
		Fee (tax excluded)	Note
Pre-Application	Checking classification of product (Class I)	JPY 10,000 per item	*Check classification and Japanese Accepted Names (JMDN) of product *If an inquiry to government administration is required, fee will be charged separately:JPY50,000 per time
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.
Importing/Post- marketing	Entrustment fee of medical device	1st year :JPY600,000 From 2nd year on:JPY300,000	
	Handling fee (product labelling, customs clearance, quality control)	Basic:JPY10,000 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 onannual 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.