

TFDA Regulatory Fee

Effective on May 1st, 2021

Item		Fee (NTD)
Medical Device Registration	Class I Medical Device 第一等級醫療器材	\$15,000
	Class II Medical Device 第二等級醫療器材	\$58,000
	Class III Medical Device 第三等級醫療器材	\$100,000
	Novel Medical Device 新醫療器材	\$130,000
Certification Amendment	Certification Amendment (Indication/ Intended Use) 效能、用途或適應症變更	\$40,000
	Certification Amendment (Model changes that may affect the efficacy and safety) 規格變更	\$35,000
	Certification Amendment (Model changes NOT affecting the efficacy and safety) 未涉及安全及效能評估之尺寸變更	\$25,000
	Manufacturing Site Amendment 製造廠變更	\$25,000
	Others Administrative Amendments (IFU contents, replacement copy for certificates/ Chinese IFU, etc.) 其他變更(說明書變更、許可證與仿單補發等)	\$10,000
	Product Certificate Extension 許可證有效期展延	\$8,000
Certificate Fee 許可證領證、補發或換發		\$1,500
Product Listing	Medical Device Listing 醫療器材登錄	\$10,000
	Annual Declaration of Medical Device 醫療器材年度申報	\$2,000
	Medical Device Listing Amendment 醫療器材登錄變更	\$8,000
QSD Application	QSD Application (New/ Renewal) 國外QSD製造許可申請/延續	\$60,000
	QSD Approval Amendment (QSD scopes, manufacturing site changes, etc.) QSD變更(包括QSD品項、製造廠地址等)	\$60,000
	Others Administrative Amendments 其他行政變更	\$10,000
Others	Classification Inquiry 屬性管理	\$3,500
	Product Certificate Authorization 許可證授權	\$4,000