

# Steps to Enter the Peruvian Market



## DIGEMID REVIEW TIMEFRAMES AND FEES

• Medical device registration	Class I	22 - 50 Business days	\$ 362.90 US Dollars or S/ 1,348.50 Soles
	Class II	44 - 60	\$ 419.50 or S/ 1,558.50
	Class III	66 - 90	\$ 487.50 or S/ 1,811.10
	In vitro MD	30 - 50	\$ 504.50 or S/ 1,886.80
• Registration certificate (per product)	All classes	15 - 30	\$ 734.50 or S/ 2,724.90
• Registration transfer (per manufacturer)	All classes	30 - 45	\$ 90.60 or S/ 336.30

The information presented in this document is based on our current understanding of the peruvian regulatory framework at the time of publishing and is subject to change.  
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# Regulatory Framework



**Perú has over 33 million residents, and is a strong, developing market for foreign manufacturers.**

- DIGEMID (Dirección General de Medicamentos, Insumos y Drogas) is the authority responsible for the control and regulation of medical devices and IVD products in Perú, in addition to medicines, biologics, dietary supplements, cosmetics, personal care products, and other healthcare supplies.
- Imported or domestic products must be registered with DIGEMID before entering our market. Pharmaceutical product registrations should be renewed every five years and cosmetics registrations every seven years.