

Steps to Enter the Peruvian Market



DIGEMID REVIEW TIMEFRAMES AND FEES

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| • 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.
JUNE 2024

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.