

Colombia is open to your medical technology. Own your market entry.

A US\$1.8 billion medical device market that imports most of what it uses, and a regulator (INVIMA) that lets foreign manufacturers hold their own registrations. With 33 years of filings before INVIMA and the SIC, SPI Américas keeps your brand, your IP and your registration under your control.

US\$1.77B

COLOMBIAN MEDICAL
DEVICE MARKET, 2025¹

US\$2.22B

PROJECTED MARKET
SIZE BY 2030¹

77%

OF THE MARKET IS
IMPORTED: US\$1.37B IN
2025¹

85%

OF COLOMBIA'S
PHARMA EXPORTS GO
TO LATIN AMERICA²

01 THE OPPORTUNITY · COLOMBIA

A market built on imports, with a hub position in Latin America.

- 1 Demand outpaces local supply.** Domestic production covers only about US\$345M of a US\$1.77B market; hospitals rely on imported technology.¹
- 2 World-class buyers.** Four Colombian hospitals rank in Latin America's top ten; 35,000+ health professionals graduate every year.¹
- 3 A regional springboard.** Over 85% of Colombia's US\$388M in pharmaceutical exports went to Latin American markets in 2025.²
- 4 A predictable regulator.** Four risk classes under Decree 4725 of 2005, 10-year registrations and 100% online filing before INVIMA.

THE DECISIVE ADVANTAGE

In Colombia, a foreign manufacturer can be the owner of its INVIMA registration.

You are not forced to hand your sanitary registration to a local distributor. Hold the title yourself, keep the freedom to appoint or change distributors, and protect the asset you invested in.

SPI structures the local representation so the registration stays in your name.

02 YOUR PARTNER · SPI AMÉRICAS

One point of contact, from dossier to resolution.

1993

FOUNDED IN
BOGOTÁ

+15,000

PERMITS,
TRADEMARKS
& PATENTS

+120

COUNTRIES
VIA
PARTNERS

1

POINT OF
CONTACT

01 · DIAGNOSE

Free initial assessment

Risk class, applicable filing, timeline and fees for your device, before you commit.

02 · REGISTER

INVIMA health registration

Dossier under Decree 4725, submission via INVIMA's Virtual Office, amendments, renewals, labeling and post-market surveillance.

03 · PROTECT

Trademarks, patents & IP

Filing before the SIC and worldwide via Madrid Protocol and PCT; defense against infringement and unfair competition.

04 · OPERATE & GROW

Legal base and partners

Company formation, contracts, compliance and data protection, plus distributor and importer search for Colombia and the region.

Built for medical device companies.

A Regulatory Affairs team specialized in medical devices, coordinating filings across Latin America.

Class I · IIA · IIB · III

10-year registration

Tecnovigilancia

+120 countries

"Above all, their deep knowledge of INVIMA procedures. Second, their high level of organization and attention to detail."

HEALTH SCIENCES CLIENT · PERU

Considering Colombia or Latin America?

Send us your device, your brand or your plan. We'll tell you which filing applies, how long it takes and what it costs. The first conversation is free.

spiamericas.com/en

Bogotá, Colombia

linkedin.com/company/spiamericas

¹ ProColombia, "Dispositivos médicos: Colombia tiene mercado y espacio para nueva inversión extranjera" (6 Oct 2026), citing sector analysis and DANE. ² ProColombia, "Mercado farmacéutico colombiano abre espacio para nueva inversión extranjera" (17 Mar 2026), citing DANE and Fitch Solutions/BMI. Market values include estimates and forecasts.