LATAM REGULATORY GUIDES · COLOMBIA

INVIMA Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Colombia

Decreto 4725 de 2005 Art. 49, Decreto 677 de 1995 accreditation and the ≤1-year currency rule, Concepto 174/2023 on cumulative apostille, and Colombia's two-day Class I clock.

Julio G. Martinez-Clark · CEO bioaccess® · Founder Amavita Sciences ·

Last updated September 9, 2026 · ~28 min read · Version 1.4.0

ON THIS PAGE

The direct answer

The Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) is Colombia's health regulator, created by Article 245 of Ley 100 de 1993 (INVIMA, Qué hacemos). Colombia's language framework is unusually flexible for a LATAM regulator: Article 49 of Decreto 4725 de 2005 allows technical and scientific device information to be filed "en inglés con traducción oficial al idioma castellano" — English with official Spanish translation (Decreto 4725 de 2005). For drugs, Decreto 677 de 1995 requires foreign documents to be accredited per the *Código de Procedimiento Civil*, be ≤1 year old, and — if not in Spanish — carry *traducción oficial* (Arts. 31 §2, 45 §2, 56 §, 67 §1) (Decreto 677 de 1995). Clinical trials run through INVIMA under Resolución

2378 de 2008 with parallel institutional ethics review; Concepto 174/2023 treats official-translator certification plus apostille as cumulative and non-waivable for legal documents (Amavita, Preclinical LATAM). Colombia's device path has the fastest low-risk clock in LATAM: Class I and IIa registrations issue in 2 business days, while Class IIb and III take 90 business days (INVIMA, Dispositivos médicos).

This guide is a complete reference for Spanish (regional-neutral es-419) regulatory translation into the INVIMA framework — drugs and devices, market access, market clearance, and clinical research. It is written for sponsors, CROs, in-house regulatory affairs teams, and CMOs conducting Colombian market entry or maintaining Colombian registrations.

A. Regulator profile

Agency name: Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) — National Institute for Drug and Food Surveillance.

Establishing statute: Article 245 of Ley 100 de 1993 (INVIMA, Qué hacemos). The verbatim statutory text of Art. 245 was not fetched — INVIMA's own institutional page cites it as the creating provision.

Jurisdictional scope: Sanitary inspection, surveillance, and control over medicines, food, medical devices, and biomedical equipment, organized through dedicated directorates (INVIMA, Qué hacemos).

Official website: invima.gov.co

Headquarters: Not stated in fetched sources.

Adjacent bodies you must coordinate with

Body	Role
Comité Institucional de Ética en Investigación (CEI) — institution-level	Art. 7 Resolución 2378/2008: every institution conducting drug research in humans must have an Institutional Ethics Committee; Art. 7 §1 requires the committee to evaluate the project, the informed-consent form, the known drug information including unexpected adverse-event reports, and all planned recruitment advertising; Art. 7 §2 routes projects from institutions without their own committee to another institution's committee (Resolución 2378 de 2008)

Body	Role
Comisión Revisora (INVIMA expert commission)	Pharmacological evaluation of new drugs; 180 business days to decide, clock interrupted by RFIs (Art. 28 Decreto 677/1995) (Decreto 677 de 1995)
Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos (CNPMDM)	Price regulation; issues the *Listado de Precios Máximos de Venta*; Circular 21 de 2026 adopts a new SISMED technical annex and Circular 22 de 2026 regulates the maximum-sale-price list, whose Art. 4 orders publication and whose Art. 8 sets entry into force on 19 August 2026 (MinSalud, Regulación de precios)
Ministerio de Salud y Protección Social (MinSalud)	Hosts the pricing regulation and the observation mechanism for the *Listado de Precios Máximos de Venta* (MinSalud)
Ministerio de Relaciones Exteriores	Legalization/apostille chain and recognition of official translators for foreign documents (Art. 44 Decreto 4725/2005) (Decreto 4725 de 2005)

Data-source note: Colombia has no ClinRegs country profile, so clinical-trial granularity in this guide comes directly from Resolución 2378/2008, Decreto 677/1995, Decreto 4725/2005, and the Amavita library.

Colombian submissions do not go to INVIMA alone. A properly-executed Colombian trial or registration requires coordinated filings across INVIMA (regulatory), the site CEI (ethics), CNPMDM plus MinSalud (economic and pricing), and the Ministerio de Relaciones Exteriores (legalization chain and translator recognition). Vendors who treat INVIMA as a single-agency submission produce packages that fail cross-body review.

B. Official language requirements

Colombia's official language is castellano (Spanish), and INVIMA reviews dossiers in es-419 (regional-neutral Spanish) — not *castellano peninsular*, not Mexican Spanish. The language rule differs sharply between drugs and devices, and vendors who don't segment the two frameworks either over-translate (wasting cost) or under-translate (triggering RFIs).

Drugs — Decreto 677 de 1995

(Decreto 677 de 1995)

- Arts. 31 §2, 45 §2, 56 §, 67 §1: foreign documents must be accredited per the *Código de Procedimiento Civil*, must be issued no more than one year before the application, and, if not

in Spanish, "requerirá traducción oficial" (require official translation).

- Art. 74: labels of imported drugs may be accepted as issued in the country of origin **provided the importer's name, composition, storage conditions and* registro *number appear in Spanish**.
- Arts. 81 and 84 (the latter for cosmetics): Spanish required.

Decreto 677/1995 has no Article 49 equivalent — no explicit English-technical-content concession for drugs.

Devices — Decreto 4725 de 2005

(Decreto 4725 de 2005)

- Art. 49: "La información técnica o científica podrá ser allegada en inglés con traducción oficial al idioma castellano" — technical/scientific information may be filed in English with official Spanish translation. This is the single most consequential language provision in the Colombian device framework, and the most permissive technical-content rule among the six LATAM regulators covered in this guide series.
- Art. 44: foreign official documents must be authenticated by the Colombian consul plus the Ministerio de Relaciones Exteriores, or apostilled, and "cuando no estén en idioma castellano requerirán traducción oficial".
- Art. 18(h): Spanish operation and maintenance manuals.
- Art. 24(c)(5): manuals in the original language and Spanish.
- Art. 54: minimum label information in Spanish.
- Art. 56: insert in Spanish.
- Art. 57: additional Spanish label for imports.

The practical band — Circular Externa 5000-0001-22

Amavita records INVIMA as tolerating English for technical annexes, with an official translator required for the legal tier (Amavita, Which Regulators Accept English Dossiers). Circular Externa 5000-0001-22 (August 2022), Section II.1 endorses full-English technical dossiers with a Spanish summary for device biocompatibility, sterility, stability, risk analyses, clinical studies, and electrical-safety reports, with graphs and diagrams requiring no translation at all (Amavita, Preclinical LATAM). The INVIMA device product page independently lists Circular 5000-001-2022 among the applicable device norms (INVIMA, Dispositivos médicos).

The biologics gap

Decreto 1782/2014 governs biological drugs, and Amavita's analysis notes it contains no language article (Amavita, Preclinical LATAM). Biologics filings default to the general Decreto 677/1995 foreign-document rule.

Register and terminology expectations

- All dossiers are reviewed in es-419 regional-neutral Spanish — not *castellano peninsular* and not Mexican Spanish (Amavita, Regulatory Language Infrastructure).
- Adverse event terminology must align with MedDRA.
- INFLESZ ≥55 is the operational readability threshold for Spanish ICFs, anchored in Resolución 2378/2008 (Amavita, INFLESZ Threshold).

C. Sworn vs certified vs simple translation

Document tier	Requirement	Legal basis
Foreign official/legal documents (devices)	Consular authentication + Ministerio de Relaciones Exteriores, or apostille, plus *traducción oficial* if not in Spanish — cumulative	Art. 44 Decreto 4725/2005 (Decreto 4725)
Foreign documents (drugs)	Accreditation per *Código de Procedimiento Civil*, ≤1 year old, *traducción oficial* if not in Spanish	Arts. 31 §2, 45 §2, 56 §, 67 §1 Decreto 677/1995 (Decreto 677)
Technical/scientific content (devices)	English permitted with official Spanish translation	Art. 49 Decreto 4725/2005 (Decreto 4725)
Preclinical/technical reports (drugs)	No sworn translator explicitly required; Decreto 677/1995 has no Art. 49 equivalent, and Decreto 1782/2014 has no language article	Amavita, Preclinical LATAM

Who qualifies as *traductor oficial*

A *traductor oficial* is recognized by the Ministerio de Relaciones Exteriores and holds ministerial certification. Concepto 174/2023 clarifies that official-translator certification plus apostille are cumulative and non-waivable for legal documents — vendors cannot substitute one for the other (Amavita, Sworn vs Certified; Amavita, Preclinical LATAM).

Apostille sequencing

The correct order is original → apostille (or consular authentication) → sworn translation → binding. Vendors who sworn-translate before apostille produce apostilles that do not attach to a valid Spanish version, forcing re-execution. Sworn translation applies only to documents that

create or prove legal standing — powers of attorney, corporate authorizations, health-authority certificates. Sworn-translating technical CMC content wastes 30-70% of translation cost (Amavita, Costly Translation Mistakes).

The ≤1-year age rule — a documented risk

Colombia's ≤1-year age rule for foreign drug documents (Arts. 31 §2, 45 §2, 56 §, 67 §1 Decreto 677/1995) is one of the two hardest "stale-document" rules in LATAM alongside Peru's 2-year expiry (Decreto 677). A foreign-authority certificate translated on day 350 and submitted on day 400 is invalid — the translation quality is irrelevant. Amavita's seventh QC gate — Document Currency — verifies that each foreign instrument is within Colombia's 1-year window at the moment of submission, not the moment of translation (Amavita, Translation QC).

D. Preclinical / non-clinical documentation — the three operational questions

Colombia's preclinical answer is asymmetric: the drug pathway and the device pathway do not treat the same document the same way, and the legal-document rule is stricter than either.

D.1 Do we have to translate every page of the preclinical stack?

Rarely. Circular 5000-0001-22 §II.1 contains the concession sponsors most often miss: graphs and diagrams require no translation. Figures, chromatograms, dose-response curves, histopathology plates, and schematic diagrams inside a study report may stay exactly as generated. Combined with INVIMA's acceptance of English technical evidence with a Spanish summary layer, that removes most of the non-clinical stack from the translation budget.

The device-vs-drug asymmetry matters. For drugs, INVIMA reviews an English CTD Module 4 with a Spanish overview. For devices, the technical file can travel further in English, but the labelling, IFU, and any patient-facing content are held to Spanish without exception — and device dossiers more frequently pull in foreign legal instruments (manufacturer declarations, ISO certificates, authorized-representative appointments) that fall into the strict tier below.

D.2 If translation IS required — is it text-only, or does it require DTP?

For legal documents, text-only but cumulative. Concepto 174/2023 establishes that the requirements for foreign legal documents are cumulative and non-waivable: apostille *and* official translation *and*, where applicable, consular legalization — one does not substitute for another. Sponsors who apostille and stop, or translate and stop, are rejected on form rather than substance.

DTP applies to device labelling, IFU, and any figure-bearing Spanish summary where the graph is retained in English under §II.1 but its caption and legend are rendered in Spanish — a caption-layer DTP task that is cheaper than full artwork rebuild but is not text-only.

D.3 If translation is NOT required — what substitutes for it?

A Spanish non-clinical summary per study, a Spanish caption and legend layer over retained English figures, and a Spanish cross-reference index into the English technical file. For devices, a Spanish essential-principles conformity table citing untranslated test reports by number.

The two regulatory pathways trigger different translation obligations

Every LATAM regulator operates two related but separate regulatory pathways for a sponsor's product: (1) clinical-trial authorization, which is what allows the investigational product to enter a clinical study on the sponsor's timeline; and (2) market-access / sanitary registration, which is what allows the commercial product to be sold. These pathways trigger different translation obligations. The most common sponsor error is applying a market-access translation obligation (device IFU, primary label, secondary packaging) to a clinical-trial dossier where that obligation is not yet in force.

Pathway 1 — clinical-trial authorization

- Protocol, IB, and ICF must be in Spanish for institutional ethics committee approval and INVIMA under Resolución 2378 de 2008.
- Foreign health-authority letters as traductor oficial + apostille per Concepto 174/2023 (cumulative and non-waivable).

Pathway 2 — market-access / sanitary registration

- Full Spanish device IFU and labelling per Decreto 4725 de 2005 labelling rules (DTP required).
- Drug labelling in full Spanish per Decreto 677 de 1995.
- Note: Art. 46 Decreto 4725/2005 requires the device to be placed on market within 36 months of registration — sponsors who file speculatively risk lapse and re-submission.

For each document class in this guide's consolidated preclinical instruction table below, check which pathway it is scoped to before authorizing translation. A document that requires DTP-scope translation for market registration may require only text-flow translation — or no translation at all — for clinical-trial authorization.

D.4 Consolidated preclinical instruction table

Document class	Spanish required?	Basis	Certification tier	DTP?	Substitute deliverable
GLP toxicology / pharmacology (drugs)	No	Circular 5000-0001-22	—	No	Spanish non-clinical summary
Graphs, diagrams, figures	No — expressly exempt	Circular 5000-0001-22 §II.1	—	Caption layer only	Spanish captions and legends
Device technical file / test reports	No	Circular 5000-0001-22	—	No	Spanish conformity table
Foreign legal instruments	Yes	Concepto 174/2023	Official translation + apostille + legalization (cumulative)	No	None
Manufacturer declarations, AR appointments	Yes	Concepto 174/2023	Official translation, cumulative	No	None
Device labelling and IFU	Yes	Device labelling rules	Certified + regulatory review	Yes	None

Where the preclinical translation risk actually sits

In the cumulative rule, not the study reports. The §II.1 figure concession is real money saved; Concepto 174/2023 is real time lost when a sponsor treats apostille and official translation as alternatives. The device-vs-drug asymmetry is the second trap: a translation scope copied from a drug filing under-covers a device filing's labelling surface.

CATEGORY 1: DRUGS

D1. Drugs — Market access (pricing, reimbursement)

Colombia's price regulation sits with the Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos (CNPMDM), operating through *circulares*:

- Circular 21 de 2026: new SISMED technical annex and reporting content
- Circular 22 de 2026: *Listado de Precios Máximos de Venta* by commercial presentation; Art. 4 orders publication of the list; Art. 8 sets the prices' entry into force on 19 August 2026

Stakeholders may file observations on the list through a form, restricted exclusively to that list (MinSalud).

Translation load for market access

Documents specific to a pricing/reimbursement submission — economic dossiers, reference-country comparators, budget-impact analyses — and the statutory decision timeline are not published on the MinSalud page. The general Decreto 677/1995 foreign-document rule (official translation, ≤1 year old) would apply to any foreign price-reference documentation (Decreto 677).

D2. Drugs — Regulatory submissions for market clearance

Modalities (Art. 14 Decreto 677/1995): *fabricar y vender*, *importar y vender*, plus other listed modalities (Decreto 677).

Two product classes (Art. 19): products whose actives are in the *normas farmacológicas* vs new drugs (Decreto 677).

Three evaluations (Art. 20): *farmacológica*, *farmacéutica*, and *legal*; Art. 26 requires all three (pharmacological + pharmaceutical + legal) for new drugs (Decreto 677).

Abbreviated route (Art. 27 §1): available where the product is registered in two or more reference countries (Decreto 677).

Statutory clocks (Decreto 677/1995) (Decreto 677):

Step	Deadline	Article
Pharmaceutical evaluation	30 business days	Art. 23(4)
Single RFI during pharmaceutical evaluation	30 business days to respond	Art. 23(3)
Legal evaluation / decision	20 business days	Art. 25(4)
Applicant response window (legal)	60 business days	Art. 25(5)

Step	Deadline	Article
Post-response decision	10 business days	Art. 25(6)
Comisión Revisora (pharmacological, new drugs)	180 business days, clock interrupted by RFIs	Art. 28

Documents requiring translation

- Foreign certificates and legal documents with *traducción oficial* and ≤1-year age (Arts. 31 §2, 45 §2, 56 §, 67 §1 Decreto 677/1995)
- Spanish label elements for imported drugs — importer name, composition, storage conditions, *registro* number (Art. 74)
- CPPs and GMP certificates: *traducción oficial* required
- CTD legal tier: full Spanish
- CTD technical modules: practical band is English with Spanish summary, but Decreto 677/1995 lacks the Art. 49 device concession — for drug technical modules, official translation is the safe default

Empirical timelines

No verified empirical INVIMA drug market-clearance clock was found in fetched sources.

Biologics extras

Decreto 1782/2014 governs biologics but contains no language article (Amavita, Preclinical LATAM) — biologics default to the Decreto 677/1995 foreign-document rule. Pediatric-specific and orphan-specific translation requirements are not enumerated in fetched sources.

D3. Drugs — Clinical research trial submissions

Authorizing agency: INVIMA. Art. 4 of Resolución 2378 de 2008 requires every drug research project in humans to be registered with INVIMA; Art. 5 prohibits starting a project without INVIMA approval or prior *visto bueno*; Art. 4 §3 requires attaching a copy of the INVIMA project registration when requesting project approval (Resolución 2378 de 2008).

Legal identity of the instrument: Resolución 002378 of 25 June 2008, Ministerio de la Protección Social, "Por la cual se adoptan las Buenas Prácticas Clínicas para las instituciones que conducen investigación con medicamentos en seres humanos", published in *Diario Oficial* 47.033 on 27 June 2008 (Resolución 2378).

GCP certification regime

- Art. 3: INVIMA verifies GCP compliance and issues a certificate, valid five years

- Art. 8: required a *Plan Gradual de Cumplimiento* within six months of issuance, attached to every research project and subject to INVIMA verification
- Art. 10: gave institutions two years to obtain GCP certification
- Art. 4 §2: requires *Sistema Único de Habilitación* certification of conditions (Resolución 2378)

Ethics framework

Dual — INVIMA plus the Institutional Ethics Committee under Art. 7 and its paragraphs. The CEI evaluates the project, the informed-consent form, known drug information including unexpected AE reports, and all planned recruitment advertising (Art. 7 §1). Projects from institutions without their own committee route to another institution's committee (Art. 7 §2) (Resolución 2378).

Documents requiring translation

- ICF: Spanish (es-419) required for CEI approval
- Protocol and Investigator's Brochure (IB / *Manual del Investigador*) for medicamentos clinical-study authorization filings: Spanish and English under Guía ASS-RSA-GU030 (now ACOM-INS110), as clarified by INVIMA derecho de petición radicado 20261299661 — see the subsection below
- Foreign clinical-trial authorizations used for reliance: apostilled/consular-authenticated + *traducción oficial* if not in Spanish
- ICF must clear the INFLESZ ≥55 readability threshold or CEI escalates (Amavita, INFLESZ Threshold)

CLINICAL-STUDY AUTHORIZATION LANGUAGE — MEDICAMENTOS (GU030 / ACOM-INS110) — SEP 2026 CLARIFICATION

Direct answer (medicamentos path only). For Colombian drug clinical-study authorization filings under Guía ASS-RSA-GU030 (now ACOM-INS110 — *Instructivo para la presentación de protocolos de estudios clínicos con medicamentos*), INVIMA's September 2026 reply to a bioaccess® derecho de petición, radicado 20261299661 (Grupo de Investigación Clínica, Dirección de Medicamentos y Productos Biológicos; signed María Isabel Vargas Velasco), clarifies:

1. The Protocol and the Investigator's Brochure (Manual del Investigador) must be submitted in Spanish and English.
2. Relevant preclinical/clinical product information is treated as consolidated in the IB; because the IB must be ES+EN, that consolidated content must be available in both languages inside the IB.
3. That is different from a general duty to fully translate into Spanish every underlying technical source report, individual study, or publication — GU030/ACOM-INS110 does not impose that blanket duty.
4. INVIMA states its 26 August 2026 communication must not be read as creating a general obligation to translate all supporting technical/source reports into Spanish.

5. INVIMA may still issue complementary information requests case-by-case on a specific expediente.
6. The reply is expressly a non-binding criterio orientador (Ley 1755 art. 28 framing) — not a binding resolution and not immunity from requerimientos.

Devices: Do not cite radicado 20261299661 as authority for device clinical investigations. Device clinical-investigation language follows the competent devices instructivo (e.g. the Resolución 4002/2007 pathway and current Dirección de Dispositivos Médicos instruments) and may differ.

Amavita Sciences™ scoping note (no rates): Default translation scope for medicamentos clinical-auth dossiers: Protocol + IB, ES+EN. Full source-report Spanish packages are optional / risk-based, not a GU030 mandate — contingency if INVIMA requires them on that expediente.

Amendments

The resolution's Technical Annex glossary defines *"Enmienda al proyecto"* as a written description of change(s) or formal clarification of a project. Art. 6 empowers INVIMA to interrupt an investigation at any time or require project modifications, on grounds (a) alteration of authorization conditions, (b) GCP non-compliance, (c) protection of trial subjects, (d) protection of public health. Art. 6 § requires communicating favourable or unfavourable results whether the investigation completes or is abandoned. The resolution as fetched sets no amendment classification, no amendment deadline, and no amendment language rule (Resolución 2378).

Statutory timelines

Resolución 2378/2008 as fetched states no day-count for INVIMA project approval. The periods it does fix are:

- Six months (compliance plan, Art. 8)
- Two years (GCP certification, Art. 10)
- Five years (certificate validity, Art. 3 §)
- ≤10 business days to schedule subsequent evaluation visits after an evaluator's initial visit (Technical Annex, Ch. II, §1.1(c))

Amavita's amendment dataset supplies the operational figures: statutory 60 business days with a typical 45 business days for amendment handling under Resolución 2378/2008 (Amavita, Amendment Cascade).

PV report language

Resolución 2378/2008 as fetched sets no adverse-event language rule and no reporting day-count. Adverse-event information is, however, part of what the Institutional Ethics Committee must evaluate (Art. 7 §1) (Resolución 2378).

CATEGORY 2: MEDICAL DEVICES

E1. Devices — Market access

The CNPMDM mandate covers *dispositivos médicos* as well as medicines by its own name, and its 2026 circulars govern the maximum-sale-price listing regime (MinSalud). Device-specific reimbursement dossiers, hospital procurement/tender translation requirements, and their timelines are not enumerated in fetched sources.

A commercial deadline that functions as an access constraint: Art. 46 Decreto 4725/2005 requires the device to be placed on the market within 36 months of registration (Decreto 4725). Vendors who obtain *registro sanitario* speculatively — without imminent commercial launch — risk registration lapse and re-submission.

E2. Devices — Regulatory submissions for market clearance

Classification: INVIMA states that device classification rests on potential risks from use and failure, considering duration of body contact, degree of invasiveness, and local vs systemic effect, following the rules of Article 7 of Decreto 4725 de 2005 (INVIMA, Dispositivos médicos). The classes are I, IIa, IIb, and III.

Note: Colombia's four-class scale (I/IIa/IIb/III) is not identical to Mexico's three-class scale (I/II/III) or Brazil's four-class scale using Roman numerals I–IV. Vendors submitting the same device in multiple LATAM markets must reclassify per jurisdiction.

Pathways (Decreto 4725/2005) (Decreto 4725):

- Art. 16: *registro sanitario* for non-controlled Class IIb/III devices
- Art. 17: automatic *registro* for Class I / IIa
- Art. 23: *permiso de comercialización* for controlled-technology biomedical equipment
- Art. 27: modalities

Statutory and published clocks

Item	Deadline	Source
Class I and IIa *registro sanitario* / renewal issuance	2 business days after filing	INVIMA device page; Art. 22(b) Decreto 4725/2005
Class IIb and III *registro sanitario*	90 business days after filing	INVIMA device page
RFI response windows	90 days	Arts. 21(c), 22 §, 29 § Decreto 4725/2005

Item	Deadline	Source
Modification response	30 business days	Art. 30 Decreto 4725/2005
BPM (GMP) inspection	≤90 business days	Art. 13 Decreto 4725/2005
Time to market after registration	36 months	Art. 46 Decreto 4725/2005

Colombia's Class I/IIa 2-business-day clock is the fastest low-risk-device path among the six LATAM regulators covered in this guide series.

Documentation by class

INVIMA's *Formato Único de Diligenciamiento de Dispositivos Médicos* requires:

- Class I devices: numerals 1–14, 17, and 18
- Class IIa: 1–18
- Class IIb / III: 1–20 as applicable
- Biomedical equipment Class I: 1–15, 18–19
- Biomedical equipment Class IIa: 1–19
- Biomedical equipment Class IIb/III uses the *permiso de comercialización* route via form code ASS-RSA-FM007 (INVIMA device page)

Reference-country homologation — Decreto 3275 de 2009

For products from the European Community, United States, Canada, Japan, Australia, or mutual-recognition partners:

- Class I / IIa: technical studies and analytical verifications, sterilization method, and disposal method are homologated
- Class IIb: clinical studies are additionally homologated (INVIMA device page)

Per-class translated documents

- Spanish operation/maintenance manuals (Art. 18(h))
- Manuals in origin language and Spanish (Art. 24(c)(5))
- Spanish label minimum content (Art. 54)
- Spanish insert (Art. 56)
- Additional Spanish label for imports (Art. 57)
- Art. 49 English-plus-official-Spanish-translation concession for technical/scientific information (Decreto 4725)

Empirical device timelines

Amavita's Class III cardiovascular case gives 32 business days (~7 weeks) total added delay for an IFU cross-reference RFI (see Section F) (Amavita, RFI Anatomy).

IVD / SaMD / combination-product extras

Not enumerated in fetched sources. The INVIMA device page lists additional applicable norms including Resolución 4816 de 2008, Resolución 4002 de 2007, Resolución 0214 de 2022, Resolución 5491 de 2017, Resolución 2968 de 2015, Resolución 4396 de 2008, Decreto 1030 de 2007, Decreto 3275 de 2009, and Decreto 582 de 2017 (INVIMA device page) — vendors bringing IVD or SaMD products should confirm current INVIMA classification guidance for those subcategories.

E3. Devices — Clinical research trial submissions

Resolución 2378/2008 is by its own title limited to research with medicines ("investigación con medicamentos en seres humanos") (Resolución 2378). A distinct device-trial instrument is listed among INVIMA's device norms — Resolución 4002 de 2 de noviembre de 2007 — but its content was not fetched. Vendors running a Colombian device trial should confirm the current device-trial pathway, document set, first-in-human vs pivotal vs post-market distinctions, and timelines directly with INVIMA. The ethics-committee requirement for device research (whether the Art. 7 CEI mandate extends by analogy from Resolución 2378/2008 or whether Resolución 4002/2007 sets a distinct rule) is not enumerated in fetched sources.

F. Common RFI / rejection patterns

Documented INVIMA case: a Class III cardiovascular device IFU where cross-reference drift (Sección 6.3 vs 6.4) triggered a *requerimiento*. Sequence:

1. Submission
2. *Requerimiento* citing IFU section-numbering inconsistency
3. Response window 30 business days; sponsor responded on day 18
4. Re-review added 14 business days
5. Total delay: 32 business days (~7 weeks)

The case cites Decreto 4725/2005 as the authority permitting English technical content with official Spanish translation (Amavita, RFI Anatomy).

The six recurring defect classes (INVIMA-applicable)

Structural-inventory and cross-reference defects are one of the six defect classes Amavita tracks across LATAM regulators (Amavita, Amendment Cascade):

1. Numeric integrity — decimal separators, unit conversions
2. Negation preservation — "not less than" ↔ "at least" flips
3. Readability below INFLESZ 55 — ICF register mismatch (Resolución 2378/2008 anchor)
4. Terminology inconsistency — MedDRA drift within the same dossier
5. Structural inventory — missing sections, cross-reference drift (the Class III cardiovascular case)
6. Jurisdictional adaptation — *castellano peninsular* delivered where es-419 required

The seventh defect class Amavita has added — Document Currency — is especially consequential for INVIMA drug submissions because of the ≤1-year foreign-document age rule.

For the full case-by-case analysis, see the six LATAM regulator rejections deconstructed blog post.

G. Timelines summary — INVIMA

Sub-category	Item	Statutory	Empirical
D1	CNPMDM maximum-price list	Circular 22 de 2026 prices effective 19 August 2026 (MinSalud)	n.a.
D2	Pharmaceutical evaluation	30 business days (Decreto 677 Art. 23(4))	n.a.
D2	Legal evaluation / decision	20 business days (Decreto 677 Art. 25(4))	n.a.
D2	Comisión Revisora (new drugs)	180 business days (Decreto 677 Art. 28)	n.a.
D2	Foreign document age limit	≤1 year (Decreto 677)	n.a.
D3	Trial approval	n.a. from Resolución 2378 (Resolución 2378)	n.a.
D3	Amendment	60 business days statutory (Amavita)	~45 business days typical (Amavita)

Sub-category	Item	Statutory	Empirical
D3	GCP certificate validity	5 years (Resolución 2378 Art. 3 §)	n.a.
E2	Class I / IIa registration	2 business days (INVIMA)	n.a.
E2	Class IIb / III registration	90 business days (INVIMA)	n.a.
E2	Device RFI response	90 days (Decreto 4725)	+32 business days total, Class III (Amavita)
E2	Modification response	30 business days (Decreto 4725 Art. 30)	n.a.
E2	BPM (GMP) inspection	≤90 business days (Decreto 4725 Art. 13)	n.a.
E2	Time to market after registration	36 months (Decreto 4725 Art. 46)	n.a.
E3	Device trials	Resolución 4002/2007 (not fetched)	n.a.

Where an item is marked n.a., that timeline is not stated in the fetched primary sources.

H. Recent regulatory changes 2023–2026

- Circular 21 de 2026 — new SISMED technical annex and reporting content (MinSalud)
- Circular 22 de 2026 — *Listado de Precios Máximos de Venta*; Art. 4 publication, Art. 8 entry into force 19 August 2026 (MinSalud)
- Circular Externa 5000-0001-22 (August 2022) — Amavita reads Section II.1 as endorsing full-English technical dossiers with Spanish summary for device technical reports; INVIMA lists it as "Circular 5000-001-2022" in its device norms (Amavita, Preclinical LATAM; INVIMA device page)
- Concepto 174/2023 — official-translator certification by the Ministerio de Relaciones Exteriores plus apostille treated as cumulative and non-waivable for legal documents (Amavita, Preclinical LATAM)
- Resolución 0214 de 2022 appears in INVIMA's current device norm list (INVIMA device page)
- Context — Argentina's ANMAT has adopted ICH E6(R3) via Disposición 7516/2025 effective 1 December 2025 (Boletín Oficial). INVIMA has not yet adopted E6(R3); Colombia's GCP framework remains anchored in Resolución 2378/2008. Sponsors running multi-country LATAM trials should track this standard-alignment gap.

I. Amavita library cross-references

- Which Regulators Accept English Dossiers — INVIMA band: English tolerated for technical annexes, official translator for legal tier
- Preclinical Translation Requirements — 9 LATAM Regulators — Circular Externa 5000-0001-22 §II.1, Decreto 4725 Art. 49, Concepto 174/2023, biologics language-article absence
- RFI Anatomy — Class III cardiovascular IFU cross-reference drift, +32 business days
- Amendment Cascade — Resolución 2378/2008 amendment path, 60 statutory / 45 typical business days
- INFLESZ Threshold — Resolución 2378/2008 as the Colombian ICF-readability anchor
- Sworn vs Certified Translation — *traductor oficial* with foreign-ministry recognition
- Regulatory Language Infrastructure — es-419 delivery variant
- Translation QC for Regulatory Dossiers — seven QC gates including Document Currency
- Costly Translation Mistakes — apostille sequencing
- Three Bands of LATAM Regulatory Translation — 12-regulator scope framing

FAQ

Does INVIMA accept English-language dossiers?

For devices, yes — Art. 49 of Decreto 4725 de 2005 allows technical and scientific information to be filed in English with official Spanish translation (Decreto 4725). Circular Externa 5000-0001-22 (August 2022) §II.1 extends this to device biocompatibility, sterility, stability, risk analyses, clinical studies, and electrical-safety reports, with graphs and diagrams requiring no translation at all (Amavita). For drugs, no equivalent concession exists — Decreto 677/1995 has no Art. 49 analogue, and technical modules default to Spanish (or English with official translation as a practical band).

What does traducción oficial actually mean in Colombia?

Traducción oficial is translation by a traductor oficial recognized by the Ministerio de Relaciones Exteriores with ministerial certification. Concepto 174/2023 clarifies that this certification plus apostille are cumulative and non-waivable for legal documents — vendors cannot substitute one for the other (Amavita, Sworn vs Certified).

What is the ≤1-year age rule?

Arts. 31 §2, 45 §2, 56 §, 67 §1 of Decreto 677/1995 require foreign documents supporting drug applications to be issued no more than one year before the application. A foreign-authority certificate translated on day 350 and submitted on day 400 is invalid regardless of translation quality (Decreto 677). Amavita's Document Currency QC gate specifically catches this defect class.

How fast can Class I and IIa devices really register — 2 business days?

Yes. INVIMA's device page and Art. 22(b) of Decreto 4725/2005 both establish a 2-business-day issuance clock for Class I and IIa registro sanitario / renewal after filing (INVIMA device page). This is the fastest low-risk device path among the six LATAM regulators. The prerequisite: submission-ready dossier compliant with the Formato Único de Diligenciamiento numerals 1–14, 17, 18 (Class I) or 1–18 (Class IIa).

How long do Class IIb and III device registrations take?

90 business days after filing (INVIMA device page). RFI response window is 90 days (Arts. 21(c), 22 §, 29 § Decreto 4725/2005).

Does the reference-country homologation route (Decreto 3275/2009) actually save time?

Yes for Class I/IIa — technical studies, analytical verifications, sterilization method, and disposal method are homologated. Yes for Class IIb — clinical studies are additionally homologated. Reference countries include the European Community, US, Canada, Japan, Australia, and mutual-recognition partners (INVIMA device page). Vendors bringing an EU-CE-marked or FDA-cleared device into Colombia can substantially shortcut the technical-file build.

How do drug registrations work — what are the evaluation stages?

Three evaluations under Decreto 677/1995 Art. 20: pharmacological, pharmaceutical, legal. New drugs require all three (Art. 26). Statutory clocks: pharmaceutical 30 business days (Art. 23(4)), legal 20 business days (Art. 25(4)), Comisión Revisora pharmacological 180 business days with clock interrupted by RFIs (Art. 28) (Decreto 677).

What Spanish variant does INVIMA expect?

es-419 (regional-neutral Spanish). Not castellano peninsular (Iberian), not Mexican Spanish. Vendors who deliver Iberian Spanish or Mexican Spanish introduce register mismatch that INVIMA reviewers can flag (Amavita, Regulatory Language Infrastructure).

What is the ICF readability threshold in Colombia?

Resolución 2378/2008 does not publish a numeric threshold, but the operational threshold Amavita has documented across LATAM ICF review is INFLESZ ≥55. ICFs below 55 trigger CEI escalation, which adds 30-90 calendar days (Amavita, INFLESZ Threshold).

Has INVIMA adopted ICH E6(R3)?

Not yet. Argentina's ANMAT is the first LATAM regulator to adopt E6(R3) via Disposición 7516/2025, effective 1 December 2025 (Boletín Oficial). Colombia's GCP framework remains anchored in Resolución 2378/2008. Sponsors running multi-country LATAM trials should track this widening standard-alignment gap.

Does INVIMA require every preclinical source report in Spanish for a drug clinical-study filing?

Not as a general GU030/ACOM-INS110 rule. The Protocol and the Investigator's Brochure must be submitted in Spanish and English, and material content consolidated in the IB must be available in both languages inside the IB. Full translation of every underlying source report, study, or publication is not stated as a general duty; INVIMA may still request complementary information case-by-case on a specific expediente. INVIMA's September 2026 reply to derecho de petición radicado 20261299661 should be cited as a non-binding criterio orientador only, and it applies to the medicamentos path — not to device clinical investigations.

About the author

Julio G. Martinez-Clark is CEO of bioaccess®, Latin America's leading medical-device clinical research organization, and founder of Amavita Sciences, the multilingual clinical operations platform. He has led first-in-human trial operations across 12 LATAM jurisdictions and built the seven-gate translation QC pipeline behind Amavita's regulatory language infrastructure.

Version history

This guide is version **1.4.0**, last updated September 9, 2026. Every substantive change to the INVIMA requirements on this page is recorded below.

v1.4.0 September 9, 2026

- Added medicamentos clinical-auth language clarification from INVIMA derecho de petición radicado 20261299661 (Protocol+IB ES+EN; no blanket full source-report translation; case-by-case; non-binding; devices excluded).
- Tightened the D3 documents-requiring-translation list so the CEI ICF rule and the GU030/ACOM-INS110 Protocol+IB ES+EN rule are stated separately.

- Added an FAQ entry on preclinical source-report translation scope for drug clinical-study filings.

v1.3.0 August 22, 2026

- Split the Section D exception list into clinical-trial authorization and market-access / sanitary registration pathways, immediately before the consolidated preclinical instruction table.
- Clarified that device IFU and labelling obligations activate at device registration, not at clinical-trial authorization.

v1.2.0 August 22, 2026

- Added Section D — Preclinical / non-clinical documentation (D.1–D.4), placed between Section C and Category 1: Drugs.
- Consolidated the sworn vs. certified vs. simple translation instruction table.
- Regenerated the downloadable PDF so it matches the on-page text.

v1.1.0 August 11, 2026

- Migrated QC copy from six gates to the seven-gate architecture (adds Document Currency).
- Added FAQ block with structured data and a pre-submission QC checklist download.

v1.0.0 July 30, 2026

- Initial publication of the regulator translation requirements guide.