LATAM REGULATORY GUIDES · ARGENTINA

ANMAT Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Argentina

What the Disposición 6677/2010 repeal changed, the five Disposición 727/2013 translator touchpoints, and why ANMAT is the most Spanish-leaning of the Big 6.

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

Last updated August 22, 2026 · ~29 min read · Version 1.3.0

ICH E6(R3) — first in LATAM

ON THIS PAGE

The direct answer

The Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) is Argentina's health regulator, created by Decreto 1490/1992 of 20 August 1992 as a decentralized public administration body with economic and financial autarky and jurisdiction throughout the national territory (Decreto 1490/1992). Argentina is the first LATAM regulator to adopt ICH E6(R3) via Disposición 7516/2025 (Boletín Oficial), effective 1 December 2025, repealing Disposiciones 6677/2010, 4008/2017, 9929/2019, and 2172/2025 plus Circulares 0001/2011, 004/2018, and the

10 June 2024 Circular. The translation consequence of the repeal is material: the old Disposición 6677/2010 §2.4 exemption that excused the Investigator's Brochure from Spanish is gone, while the new text carries no general Spanish rule and mandates Spanish only for recruitment advertising, the investigational product label, and the principal investigator's CV (Amavita, Preclinical LATAM). For drugs, Disposición 5755/1996 Art. 8 requires foreign health-authority commercialization documents to be legalized and translated by a *traductor público matriculado* (Disposición 5755/1996). ANMAT is the most Spanish-leaning of the six LATAM regulators covered in this guide series and has the broadest sworn-translation scope in the region (Amavita, Which Regulators Accept English Dossiers).

This guide is a complete reference for Argentine Spanish regulatory translation into the ANMAT 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 Argentine market entry or maintaining Argentine registrations.

A. Regulator profile

Agency name: Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) — National Administration of Drugs, Foods, and Medical Devices.

Establishing statute: Decreto 1490/1992 of 20 August 1992, Buenos Aires. Art. 1 declares actions to control the quality and sanitary condition of products used in human medicine, food, and cosmetics to be of national interest; Art. 2 creates ANMAT within the Secretaría de Salud of the Ministerio de Salud y Acción Social as an *Organismo Descentralizado de la Administración Pública Nacional*, technically and scientifically dependent on the Secretaría de Salud, with economic and financial autarky and jurisdiction throughout the national territory (Decreto 1490/1992).

Jurisdictional scope (Art. 3 Decreto 1490/1992):

(a) drugs, chemicals, reagents, pharmaceutical forms, medicines, diagnostic elements, biomedical materials and technology, and every other product used in human medicine (b) packaged foods including additives, colourants, sweeteners, and food-contact materials, and household-use products (c) hygiene, toiletry, and cosmetic products and their raw materials (d) efficacy vigilance and adverse-effect detection across (a)–(c) (e) control of supply, production, manufacture, fractionation, import/export, storage, and commercialization activities (f) prevention and health-protection actions (g) any other action serving Art. 1 (Decreto 1490/1992)

Art. 8(k) empowers ANMAT to authorize, certify, register, and enrol those products; Art. 8(ll) to register/authorize/license the natural and legal persons in the supply chain; Art. 8(m) to set and collect fees.

Official website: anmat.gob.ar

Headquarters: Decreto 1490/1992 as fetched does not state a seat or domicile.

Adjacent bodies you must coordinate with

Body	Role
Dirección de Investigación Clínica y Gestión del Registro de Medicamentos (within ANMAT)	Under Art. 5 of Disposición 7516/2025, this Directorate evaluates protocols and issues the technical report recommending authorization or rejection (a); may require protocol modifications before or during the study (b); authorizes investigators and sites (c); maintains the database of approved, withdrawn, and denied studies and GCP inspection results (d); intervenes via Comercio Exterior for study-material import/export (e); evaluates protocol amendments (f); evaluates periodic and final reports and non-compliance reports (g); receives and analyses safety information (h); inspects sites for first-in-human authorization (j); may suspend a study at a site (m); may convene expert advisory committees (n); harmonizes criteria with the jurisdictional accreditation body and the CRI/CEIs (o); promotes Good Reliance Practices (p); and may propose procedures modifying deadlines such as expedited authorization or abbreviated evaluation during a declared health emergency (r) (Disposición 7516/2025)
CRI / CEI — jurisdictional accreditation body and ethics committees	Named in Art. 5(o) of Disposición 7516/2025 as ANMAT's counterparties for criteria harmonization on clinical research; ethics review sits with jurisdiction-accredited committees, not ANMAT (Disposición 7516/2025)
Colegio de Traductores Públicos	Registration and legalization body for the *traductor público* whose translation ANMAT requires for foreign legal instruments (Amavita, Sworn vs Certified)
MERCOSUR / Grupo Mercado Común	Source of the device framework: Disposición 2318/2002 Art. 1 adopts the *Reglamento Técnico MERCOSUR de Registro de Productos Médicos* (GMC Resolution No. 40/00) as Annex I, and Art. 2 requires notification to the MERCOSUR Administrative Secretariat in Montevideo (Disposición 2318/2002)

Data-source note: Argentina has no ClinRegs country profile. All clinical-trial granularity in this guide comes directly from Disposición 7516/2025 (Boletín Oficial notice), Disposiciones 5755/1996 and 2318/2002, Decretos 1490/1992 and 150/1992, and the Amavita library.

Argentine submissions do not go to ANMAT alone. A properly-executed Argentine trial or registration requires coordinated filings across ANMAT (regulatory), the jurisdictional CEI (ethics),

the Colegio de Traductores Públicos (translator legalization), and, for MERCOSUR device notifications, the MERCOSUR Administrative Secretariat.

B. Official language requirements

Argentina's official language is Spanish (Argentine variant), and ANMAT is the most Spanish-leaning of the six LATAM regulators covered in this guide series with the broadest sworn-translation scope in the region (Amavita, Which Regulators Accept English Dossiers).

Drugs — Disposición 5755/1996 Art. 8

Commercialization-evidence documents (free-sale certificate, packaging, formulary inclusion, REM certificate number) must be originals or authenticated photocopies. If issued by a foreign health authority they require legalization, and **if written in a language other than Spanish they must be accompanied by a translation made by a* traductor público matriculado*** (Disposición 5755/1996).

Drugs — Decreto 150/1992

Decreto 150/1992 as published contains no language or translation requirement for dossiers, inserts, technical documentation, certificates, or patient information (Decreto 150/1992, texto actualizado). The Spanish rule for drug submissions is imposed at the procedural layer by Disposición 5755/1996.

Clinical trials — Disposición 7516/2025 (effective 1 December 2025)

Disposición 7516/2025 as published in the Boletín Oficial carries Annexes I–VI that are not reproduced in the notice itself, so the Spanish-language requirements for protocol, IB, ICF, advertising, and investigator CV are not verifiable from the Boletín Oficial page alone (Disposición 7516/2025).

Amavita's reading of the annexes is that Disposición 7516/2025 contains no general Spanish rule and mandates Spanish only for:

- Recruitment advertising
- Investigational product label
- Principal investigator's CV

The repeal of Disposición 6677/2010 removes the §2.4 exemption that had excused the Investigator's Brochure from Spanish (Amavita, Preclinical LATAM). Vendors reading this repeal-

and-replace as a language liberalization are missing the operational effect: the IB now has no explicit exemption, and the practical band is that Argentine reviewers expect Spanish for protocol and IB despite the absence of a categorical statutory Spanish rule.

Devices — Disposición 2318/2002

The published text of Disposición 2318/2002 (Arts. 1–3 plus the Annex fragments retrieved) does not state a Spanish labelling/IFU rule, a *traductor público* requirement, a legalization rule, or review day-counts (Disposición 2318/2002). Amavita records the region-wide rule — device IFU and labelling must be in the national language everywhere in LATAM, including under ANMAT (Amavita, Which Regulators Accept English Dossiers).

Register and terminology expectations

- All dossiers are reviewed in Argentine Spanish — not *castellano peninsular*, not Mexican Spanish, not es-419 regional-neutral (Amavita, Regulatory Language Infrastructure).
- The register expectation is *español rioplatense* voseo where appropriate to patient-facing text and standard formal-register Spanish for regulatory text.
- Adverse event terminology must align with MedDRA.
- INFLESZ ≥55 is the operational readability threshold for Spanish ICFs, anchored in Resolución 1480/2011 (Amavita, INFLESZ Threshold).

C. Sworn vs certified vs simple translation

Document tier	Requirement	Legal basis
Foreign health-authority commercialization evidence	Original/authenticated copy + legalization + translation by *traductor público matriculado*	Art. 8 Disposición 5755/1996 (Disposición 5755/1996)
Foreign legal instruments (clinical research)	*Traductor público matriculado* + Colegio de Traductores Públicos registration + Colegio legalization + apostille — applied only to foreign legal instruments	Disposición 727/2013 imposes the translator requirement in five places (Amavita, Preclinical LATAM)
Technical / preclinical test reports	No translator clause — authenticated copies signed/declared by the legal representative and technical director	Art. 3(e) Disposición 727/2013 (Amavita, Preclinical LATAM)

Document tier	Requirement	Legal basis
Protocol, IB (post-1 Dec 2025)	No categorical Spanish rule in Disposición 7516/2025 as fetched; practical band is Spanish	Amavita, Preclinical LATAM
Recruitment advertising, IP label, PI CV	Spanish required	Disposición 7516/2025 Annexes (as read by Amavita) (Amavita, Preclinical LATAM)
Sworn-translator declaration in amendments	Was required for certain document types under the (now repealed) Disposición 6677/2010 framework	Amavita, Amendment Cascade

Who qualifies as *traductor público*

A *traductor público* is registered with the Colegio de Traductores Públicos and requires Colegio legalization of each translation. This is the broadest sworn scope among LATAM regulators — ANMAT extends the sworn-translation touchpoints across more document classes than any other of the six (Amavita, Sworn vs Certified).

The five Disposición 727/2013 translator touchpoints

Disposición 727/2013 imposes the *traductor público* requirement in five places, applied to foreign legal instruments — powers of attorney, corporate authorizations, health-authority certificates, GMP certificates, and CPPs. The Art. 3(e) technical-report carve-out — authenticated copies signed/declared by the legal representative and technical director — is the operational escape valve that keeps technical/preclinical test reports outside the sworn-translation scope (Amavita, Preclinical LATAM).

Apostille + Colegio legalization sequence

The correct order is **original → apostille →* traductor público *translation → Colegio legalization → binding*. Vendors who translate before apostille produce apostilles that do not attach to a Spanish version, forcing re-execution. Vendors who skip Colegio legalization produce translations that ANMAT reviewers can object to on procedural grounds (Amavita, Costly Translation Mistakes).

Document Currency (seventh QC gate)

Foreign certificates, apostilles, and notarized instruments must be within their jurisdictional validity window at the moment of submission. Argentina does not carry an explicit foreign-document expiry rule the way Peru does (2-year rule) or Colombia does (≤1-year rule for drug documents), but stale documents trigger ANMAT observation. Amavita's seventh QC gate — Document Currency — verifies validity-window compliance at release (Amavita, Translation QC).

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

Argentina is the strictest of the seven on legal instruments and, at the same time, offers one of the cleanest carve-outs for technical and preclinical reports. Getting the two apart is the entire exercise.

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

No — Art. 3(e) of Disposición 727/2013 provides an authenticated-copy carve-out for technical and preclinical reports. The sponsor files an authenticated copy of the report rather than a Colegio-legalized sworn translation of it. GLP toxicology, pharmacology, ADME, toxicokinetics, and stability-supporting non-clinical evidence travel under this route.

The carve-out stops at the legal shell. Disposición 5755/1996 Art. 8 is the strictest translator rule in the region: foreign legal instruments require translation by a *traductor público* registered with the Colegio de Traductores Públicos, with the Colegio's legalization on the translation itself. Not a certified translation, not a notarized one — Colegio-legalized.

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

Text-only for the sworn tier, but with a procedural chain: apostille on the source document, sworn translation, Colegio legalization of the translation, then filing. Each link is separately verifiable and separately rejectable.

The clinical surface tightened in 2025. Disposición 7516/2025 adopts ICH E6(R3) and repeals the §2.4 Investigator's Brochure exemption in Disposición 6677/2010 — the exemption sponsors relied on to keep the IB in English. Clinical-document translation scope therefore expanded even as the preclinical carve-out stayed intact: an IB that contains the non-clinical summary now falls on the translated side of the line.

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

An authenticated copy under Art. 3(e), accompanied by a Spanish study-level summary and an index that ties each report to the safety conclusion it supports. For device filings, a Spanish essential-requirements table over untranslated engineering evidence.

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

- Under Disposición 7516/2025 (effective 1 December 2025) adopting ICH E6(R3), protocol and ICF must be in Spanish.
- IB acceptance in source language is now tighter than the pre-2025 Disp. 6677/2010 §2.4 exemption allowed.
- Foreign health-authority letters require traductor público matriculado + Colegio legalization.

Pathway 2 — market-access / sanitary registration

- Full Spanish device IFU and labelling per the Disposición 2318/2002 framework (DTP required).
- Drug labelling in full Spanish per Disposición 5904/1996.

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 reports	No	Disp. 727/2013 Art. 3(e)	Authenticated copy	No	Spanish study summary
ADME / toxicokinetics	No	Disp. 727/2013 Art. 3(e)	Authenticated copy	No	Spanish tabulated summary
Device engineering / biocompatibility	No	Disp. 727/2013 Art. 3(e)	Authenticated copy	No	Essential-requirements table

Document class	Spanish required?	Basis	Certification tier	DTP?	Substitute deliverable
Investigator's Brochure	Yes (since 2025)	Disp. 7516/2025 repealing Disp. 6677/2010 §2.4	Certified, MD-reviewed	No	None
Protocol, ICF, amendments	Yes	Disp. 7516/2025 / ICH E6(R3)	Certified, MD-reviewed	No	None
Foreign legal instruments, powers, certificates	Yes	Disp. 5755/1996 Art. 8	*Traductor público* + Colegio legalization	No	None
Labelling and IFU	Yes	ANMAT labelling rules	Certified + regulatory review	Yes	None

Where the preclinical translation risk actually sits

In the 2025 clinical expansion, not the preclinical stack. Sponsors working from a pre-2025 scope keep the IB in English and get an *observación*; sponsors who fear Art. 8 translate toxicology reports that Art. 3(e) lets them file as authenticated copies. The Colegio legalization step — separate from the sworn translation itself — is the single most common missing link in Argentine filings.

CATEGORY 1: DRUGS

D1. Drugs — Market access (pricing, reimbursement, HTA)

No Argentine pricing, reimbursement, or HTA body, document set, or timeline was verified from a fetched primary source in this session. Decreto 1490/1992 assigns ANMAT no price-setting function among its Art. 3 and Art. 8 powers (Decreto 1490/1992); Art. 8(m) is limited to ANMAT's own fees and charges.

This is a genuine gap in the fetched primary sources, not a finding that the category does not exist. Argentina does operate reimbursement and public-sector procurement mechanisms — vendors should confirm current pricing/HTA framework and document translation requirements separately with Ministerio de Salud and the relevant provincial health authorities.

D2. Drugs — Regulatory submissions for market clearance

Argentina operates a three-route drug registration framework under Decreto 150/1992.

Three statutory routes (Decreto 150/1992) (Decreto 150/1992):

Route	Content
Art. 3	Ordinary REM registration. Sworn-declaration content: (a) product data — proposed name, defined and verifiable formula, pharmaceutical form(s), pharmacological classification with WHO international code reference where one exists, dispensing condition; (b) technical information — control method, shelf life, GMP-compliant manufacturing method, bioavailability data; (c) draft labels with laboratory name/address, technical director, product and generic name in equal size and prominence, formula per dosage unit or percentage, content per sales unit, expiry, storage, sales condition, batch and manufacturing series, and the legend "MEDICAMENTO AUTORIZADO POR EL MINISTERIO DE SALUD Y ACCION SOCIAL, CERTIFICADO Nº"; (d) draft inserts reproducing non-variable label text plus pharmacological/therapeutic actions, precise clinical indications, warnings, precautions, antagonisms/antidotes/interactions where applicable, adverse effects, usual posology, maximum and minimum doses, administration route, and presentations; (e) for specialties imported from Annex II countries, a certificate from the origin-country health authority issued per WHO Resolution WHA41.18.1988. Art. 3 also covers (I) products similar to those already in the REM and (II) products authorized for public consumption in at least one Annex I country.
Art. 4	Automatic registration for import of specialties authorized for public consumption in the domestic market of at least one Annex I country. Requires the current official authorization certificate, the Art. 3(c) and 3(d) documentation, and bioavailability data. Registration is for import and commercialization only; local manufacture of similars/bioequivalents must go through Art. 3.

Route	Content
Art. 5	Requires efficacy and safety documentation in addition to Art. 3 content, for (a) locally manufactured specialties novel in Argentina, (b) Annex II imports without a similar in the register, (c) imports manufactured in countries in neither Annex I nor Annex II and not authorized in an Annex I country.

Statutory clock

The Ministry has **120 consecutive days (*días corridos*) from filing to decide an Art. 3 registration, excluding Art. 4 and Art. 5 regimes. For Annex II imports the clock runs from verification of the manufacturing plant, which must occur within 60 days** of filing (Decreto 150/1992).

Procedural implementation (Disposición 5755/1996) (Disposición 5755/1996):

- Art. 1: applies to REM applications under Decreto 150/92 Arts. 3, 4, and 5
- Art. 2: makes the Annex I procedure flowchart mandatory
- Art. 3: Art. 3/Art. 4 applications may not exceed the periods in Annex II (Annex II day-counts not published in fetched text — n.a.); because Decreto 150/92 sets no period for Art. 5 applications, the Disposición imposes none
- Art. 4: approves the Annex III information/document requirements per procedure type and gives form entries the status of a sworn declaration
- Art. 10: approves the technical-evaluation, acceptance, objection, and rejection forms (Annex IV)
- Art. 14: requires one legal opinion per application from the Dirección de Asuntos Jurídicos (Annex V)
- Art. 15: makes acceptance/objection/rejection reports the technical basis for sustaining, interrupting, or denying registration
- Arts. 16–17: approve the authorizing and denying disposition templates (Annexes VI–VII)

Similarity definitions

- Art. 5 Disposición 5755/1996: defines a *similar* specialty (same active(s), concentration(s), pharmaceutical form(s), route, therapeutic indication, dosage regimen, equivalence to the reference), permitting differences in size/shape, excipients, shelf life, and primary packaging
- Art. 6: adds two alternative definitions accepted for Art. 3 procedures (including salt/ester variation with the same therapeutically active molecular structure)
- Art. 7: defines a *similar pharmaceutical form* (Disposición 5755/1996)

Documents requiring translation

The Art. 8 chain — legalization plus *traductor público matriculado* translation for foreign health-authority documents (Disposición 5755/1996). CPPs and GMP certificates fall inside this chain.

Empirical timelines

Not verified from fetched sources.

Pediatric / orphan / biosimilar extras

Not enumerated in fetched sources.

D3. Drugs — Clinical research trial submissions

Governing instrument as of 1 December 2025: Disposición 7516/2025, dated 8 October 2025 and published 9 October 2025, signed by Nelida Agustina Bisio (Disposición 7516/2025).

The five key articles

- Art. 1: approves the rules on Buenas Prácticas Clínicas and on the evaluation and oversight of clinical pharmacology studies for registration purposes, in Annexes I–V
- Art. 2: approves the glossary (Annex VI)
- Art. 3: adopts ICH E6(R3) for registrational clinical trials, complemented by local regulatory requirements in Annex II
- Art. 4: scope — registrational clinical pharmacology studies and studies on already-registered medicines evaluating, for registration purposes, a new indication, a higher concentration, a new posology, a new pharmaceutical form, or any other post-registration modification requiring clinical-trial data; covers Phase I, II, and III and phase variations; excludes bioequivalence/bioavailability studies under specific rules, non-interventional studies, and non-registrational studies. Sponsors must obtain ANMAT authorization before conducting covered studies
- Art. 7: repeals Disposiciones ANMAT 6677/2010, 4008/2017, 9929/2019, and 2172/2025, Circulares 0001/2011 and 004/2018, and the Circular of 10 June 2024
- Art. 8: enters into force 1 December 2025; applications pending on that date are evaluated under the repealed rules

Argentina is first in LATAM for ICH E6(R3)

This is the single largest LATAM regulatory change in the 2023–2026 window. Argentina beats every other LATAM regulator to E6(R3) adoption:

- ANVISA (Brazil) has adopted E6(R2) but has not yet implemented E6(R3) (ClinRegs Brazil)
- COFEPRIS (Mexico), INVIMA (Colombia), ISP (Chile), and DIGEMID (Peru) have not adopted E6(R3) at the time of this guide

Sponsors running multi-country LATAM trials must now maintain two GCP standards in parallel — E6(R2) for the majority of LATAM and E6(R3) for Argentina — until the other regulators align. For pivotal trials with Argentine sites, sponsors should upgrade to E6(R3) processes across the entire study to avoid a two-track quality system.

Authorizing agency and ethics framework

ANMAT authorizes; the ethics layer is jurisdictional. Art. 5(o) names the *organismo central de acreditación jurisdiccional* and the CRI/CEIs as the bodies with which ANMAT harmonizes criteria. Art. 5(j) reserves site inspection for first-in-human authorization to ANMAT (Disposición 7516/2025).

Documents requiring translation (as read by Amavita)

- Spanish required: recruitment advertising, investigational product label, principal investigator's CV
- No categorical Spanish rule: protocol, IB, ICF — but practical band is Spanish
- Foreign legal instruments: *traductor público matriculado* + Colegio legalization + apostille (Disposición 727/2013) (Amavita, Preclinical LATAM)

Amendments

Art. 5(f) assigns amendment evaluation to the Dirección; the substantial/non-substantial taxonomy and its day-counts live in the unpublished Annexes, so authoritative day-counts are not verifiable from the Boletín Oficial notice (Disposición 7516/2025).

Amavita's dataset records ~30 business days as typical for non-substantive amendments and characterizes ANMAT as the fastest amendment responder among the six LATAM regulators, under the (now repealed) Disposición 6677/2010 framework (Amavita, Amendment Cascade).

Safety reporting

Art. 5(h) obliges the Dirección to receive and analyse relevant safety information and implement preventive or corrective actions; Art. 5(g) covers periodic, final, and non-compliance reports. Day-counts and language rules for safety reporting are in the unpublished Annexes (Disposición 7516/2025).

ICF readability

Amavita anchors Argentine ICF practice to Resolución 1480/2011, with the operational INFLESZ ≥55 threshold (Amavita, INFLESZ Threshold).

Good Reliance Practices and health-emergency deadlines

- Art. 5(p) formalizes Good Reliance Practices — ANMAT can rely on foreign-regulator decisions in its own authorization pathway
- Art. 5(r) allows procedures modifying deadlines (expedited authorization, abbreviated evaluation) in declared health emergencies (Disposición 7516/2025)

CATEGORY 2: MEDICAL DEVICES

E1. Devices — Market access

Not verified from fetched sources — no Argentine device reimbursement, procurement, or tender framework was confirmed in this session. Vendors should confirm current provincial and PAMI (national retiree health) procurement rules separately.

E2. Devices — Regulatory submissions for market clearance

Framework: Disposición 2318/2002 of 23 May 2002 approves the *Reglamento Técnico MERCOSUR de Registro de Productos Médicos* (GMC Resolution 40/00) as Annex I (Art. 1), orders MERCOSUR notification (Art. 2) and publication (Art. 3), signed by Manuel R. Limeres, issued under Decretos 1490/92 and 197/02 (Disposición 2318/2002).

Classification

Annex I, Part 2, point 1 places *productos médicos* in Classes I, II, III, and IV by intrinsic risk to consumer, patient, operator, or third parties, applying the Annex II classification rules. Point 2 gives the competent health authority the tie-break on doubtful classification. Point 3 allows rule updates via MERCOSUR administrative procedure. Annex II, I, point 6 maps the earlier three-class scale: old Class I → Class I, old Class II → Class II, old Class III → Classes III and IV (Disposición 2318/2002).

Argentina's four-class MERCOSUR scale (I/II/III/IV) is the same scale used by Brazil under ANVISA — this alignment simplifies MERCOSUR-block dual submissions.

Representative Annex II classification rules (Disposición 2318/2002):

- Rule 1: non-invasive devices default to Class I
- Rule 2: non-invasive conduction/storage devices are Class II when connected to Class II+ active devices or used for blood/fluids/organs/tissues, otherwise Class I
- Rule 3: devices altering biological/chemical composition of blood or fluids for introduction into the body are Class III, dropping to Class II for filtration, centrifugation, gas, or heat exchange
- Rule 4: injured-skin contact devices split I / III / II by mechanism
- Rule 5: body-orifice invasive devices scale by duration with named anatomical exceptions
- Rules 6 and 7: transitional and short-term surgically invasive devices are Class II with Class III/IV escalations for cardiac/central-circulatory and CNS contact, ionizing radiation, biological effect/absorption, and drug delivery
- Rule 8: implantable and long-term surgically invasive devices are Class III

Language, legalization, and timelines

The published text of Disposición 2318/2002 (Arts. 1–3 plus Annex fragments retrieved) does not state a Spanish labelling/IFU rule, a *traductor público* requirement, a legalization rule, or review day-counts (Disposición 2318/2002). Amavita's region-wide rule applies: device IFU and labelling must be in the national language, including under ANMAT (Amavita, Which Regulators Accept English Dossiers).

Empirical device timelines

Amavita's ANMAT Class III neurostimulation case gives a day-45 hold-release figure (see Section F) (Amavita, RFI Anatomy).

IVD / SaMD / combination-product extras

Not enumerated in fetched sources.

E3. Devices — Clinical research trial submissions

Disposición 7516/2025 is by its Art. 4 scope limited to clinical pharmacology studies with medicines for registration purposes (Disposición 7516/2025). No Argentine device-trial instrument, document set, first-in-human vs pivotal vs post-market distinction, ethics pathway, or timeline was verified in this session — vendors running an Argentine device trial should confirm the applicable framework directly with ANMAT.

F. Common RFI / rejection patterns

Documented ANMAT case: a Class III neurostimulation device where a negation dropout turned "may not be used" into "puede utilizarse" — the *no* was lost between English source and Spanish target. Sequence:

1. Submission
2. *Observación* citing the negation defect, and a hold
3. QC investigation: 14 days
4. IFU reissue: 7 days
5. CAPA: 7 days
6. Hold released on day 45
7. Event triggered a supplementary ISO 13485 audit and an estimated ~USD 45,000 total impact (Amavita, RFI Anatomy)

Negation preservation is one of the six defect classes Amavita tracks across LATAM regulators.

The six recurring defect classes (ANMAT-applicable)

(Amavita, Amendment Cascade; Amavita, Regulatory Language Infrastructure):

1. Numeric integrity — decimal separators, unit conversions
2. Negation preservation — "may not be used" ↔ "puede utilizarse" flips (the neurostimulation case)
3. Readability below INFLESZ 55 — Resolución 1480/2011 anchor
4. Terminology inconsistency — MedDRA drift within the same dossier
5. Structural inventory — missing sections in the Spanish delivery
6. Jurisdictional adaptation — *castellano peninsular* or generic Latin American Spanish delivered where Argentine Spanish required

The seventh defect class Amavita has added — Document Currency — captures stale foreign certificates, apostilles, and notarizations that were valid when translated but expired between translation and submission.

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

G. Timelines summary — ANMAT

Sub-category	Item	Statutory	Empirical
D1	Pricing/HTA	n.a.	n.a.
D2	Art. 3 REM registration	120 días corridos (Decreto 150/1992)	n.a.
D2	Annex II plant verification	60 days from filing (Decreto 150/1992)	n.a.
D2	Art. 4 automatic registration (Annex I country)	Automatic (Decreto 150/1992)	n.a.
D2	Art. 5 route (novel/non-Annex)	No statutory period (Disposición 5755/1996 Art. 3)	n.a.
D3	Trial authorization	n.a. (Annexes unpublished) (Disposición 7516/2025)	n.a.

Sub-category	Item	Statutory	Empirical
D3	Non-substantive amendment	n.a. (Annexes unpublished)	~30 business days typical — fastest LATAM responder (Amavita)
E2	Device registration (all classes)	n.a. (Disposición 2318/2002)	Class III hold released day 45 (Amavita)
E3	Device trials	n.a.	n.a.

Where an item is marked n.a., that timeline is not stated in the fetched primary sources or lives in the unpublished Annexes of Disposición 7516/2025.

H. Recent regulatory changes 2023–2026

- Disposición 7516/2025 (8 October 2025, published 9 October 2025, in force 1 December 2025) is the single largest change among the six LATAM regulators in this window. It approves a new GCP and clinical-pharmacology oversight framework, adopts ICH E6(R3) — Argentina becomes the first LATAM regulator to do so — and repeals Disposiciones 6677/2010, 4008/2017, 9929/2019, and 2172/2025, plus Circulares 0001/2011, 004/2018, and the 10 June 2024 Circular (Disposición 7516/2025).
- Translation consequence of the repeal: removes the Disposición 6677/2010 §2.4 exemption of the Investigator's Brochure from Spanish, while the new text carries no general Spanish rule and mandates Spanish only for recruitment advertising, the IP label, and the PI's CV (Amavita, Preclinical LATAM).
- Art. 5(p) of Disposición 7516/2025 formalizes Good Reliance Practices, which changes the strategic value of ANMAT authorization for multi-country LATAM programs.
- Art. 5(r) allows procedures modifying deadlines (expedited authorization, abbreviated evaluation) in declared health emergencies (Disposición 7516/2025).

The Amavita interpretation: the Disposición 7516/2025 Annexes are not published in the Boletín Oficial notice, and Amavita's reading depends on annex text obtained from ANMAT's own materials. Sponsors should confirm current annex text with ANMAT for any submission where the language classification of a document type is decisional.

I. Amavita library cross-references

- Which Regulators Accept English Dossiers — ANMAT most Spanish-leaning, broadest translation scope, sworn + legalized legal documents

- Sworn vs Certified Translation — *traductor público* + Colegio registration + legalization
- Preclinical Translation Requirements — 9 LATAM Regulators — Disposición 727/2013 five translator touchpoints and Art. 3(e) technical-report carve-out; Disposición 6677/2010 §2.4 and its repeal by Disposición 7516/2025
- RFI Anatomy — Class III neurostimulation negation dropout, day-45 hold release, ~USD 45,000 impact
- Amendment Cascade — Disposición 6677/2010 framework as historical baseline, ~30 business days, fastest responder
- INFLESZ Threshold — Resolución 1480/2011 as the Argentine ICF-readability anchor
- Regulatory Language Infrastructure — Argentine Spanish variant delivery
- Translation QC for Regulatory Dossiers — seven QC gates including Document Currency
- Costly Translation Mistakes — apostille + Colegio legalization sequencing
- Three Bands of LATAM Regulatory Translation — 12-regulator scope framing

FAQ

Has ANMAT really adopted ICH E6(R3)? What does this mean operationally?

Yes — Disposición 7516/2025 at Art. 3 adopts ICH E6(R3) for registrational clinical trials, effective 1 December 2025 (Boletín Oficial). Argentina is the first LATAM regulator to do so. Operationally: sponsors running multi-country LATAM trials must now maintain two GCP standards in parallel — E6(R2) for the majority of LATAM and E6(R3) for Argentina — until the other regulators align. For pivotal trials with Argentine sites, upgrading to E6(R3) processes across the entire study avoids a two-track quality system.

Does ANMAT accept English-language dossiers?

Barely. ANMAT is the most Spanish-leaning of the six LATAM regulators and has the broadest sworn-translation scope in the region (Amavita, Which Regulators Accept English Dossiers). Drugs: Disposición 5755/1996 Art. 8 requires Spanish translation by traductor público matriculado for foreign health-authority commercialization documents (Disposición 5755/1996). Clinical trials post-1 December 2025: Disposición 7516/2025 has no general Spanish rule but mandates Spanish for recruitment advertising, the investigational product label, and the PI's CV, with the IB no longer categorically exempt.

What is a traductor público matriculado and how is it different from other LATAM sworn translators?

A traductor público is registered with the Colegio de Traductores Públicos and requires Colegio legalization of each translation. The Colegio legalization step is unique to Argentina — Colombia's traductor oficial is recognized by the Ministerio de Relaciones Exteriores directly, Mexico's perito traductor is authorized at state judicial level, and Brazil's sworn translator is a tradutor público juramentado registered with the state commercial board (Junta Comercial). Argentine legal documents require the Colegio-legalization stamp on the translation itself (Amavita, Sworn vs Certified).

What is Article 3 vs Article 4 vs Article 5 registration under Decreto 150/1992?

Three drug-registration routes (Decreto 150/1992): - Art. 3 — ordinary REM registration, 120 días corridos, for products similar to those already registered or authorized in an Annex I country - Art. 4 — automatic registration for import of specialties authorized in the domestic market of at least one Annex I country; requires the origin-country authorization certificate plus Art. 3(c) and 3(d) documentation - Art. 5 — for novel Argentine products, Annex II imports without a similar in the register, or non-Annex-country imports; requires efficacy and safety documentation on top of Art. 3 content; no statutory period

What did the repeal of Disposición 6677/2010 change about clinical trial translation?

The §2.4 exemption that had excused the Investigator's Brochure from Spanish is gone. Disposición 7516/2025 carries no general Spanish rule, but the IB no longer has an explicit exemption. Practical band: Spanish IB is expected. Vendors reading this repeal as a language liberalization are missing the operational effect (Amavita, Preclinical LATAM).

What Spanish variant does ANMAT expect?

Argentine Spanish — español rioplatense. Not castellano peninsular, not Mexican Spanish, not generic es-419 regional-neutral. Vendors who deliver Iberian Spanish or generic Latin American Spanish introduce register mismatch that ANMAT reviewers can flag (Amavita, Regulatory Language Infrastructure).

What is Good Reliance Practices under Disposición 7516/2025 Art. 5(p)?

Good Reliance Practices formalizes ANMAT's ability to rely on foreign-regulator decisions in its own authorization pathway. In an ICH E6(R3) framework with formalized reliance, ANMAT can, at its discretion, accept foreign-regulator evaluations as evidence in its own decision — reducing duplication for sponsors bringing FDA/EMA-authorized programs into Argentina (Disposición 7516/2025).

What device classification does ANMAT use?

Four classes (I, II, III, IV) under the MERCOSUR framework in Disposición 2318/2002, Annex I, Part 2 (Disposición 2318/2002). This aligns with Brazil's ANVISA four-class scale, simplifying MERCOSUR-block dual submissions.

What is the ICF readability threshold in Argentina?

Resolución 1480/2011 anchors ICF practice. The operational threshold Amavita has documented across LATAM ICF review is INFLESZ ≥55. ICFs below 55 trigger CEI escalation (Amavita, INFLESZ Threshold).

What is the highest-risk defect class for ANMAT submissions?

Negation preservation. Amavita's documented Class III neurostimulation case cost a day-45 hold release, a supplementary ISO 13485 audit, and an estimated ~USD 45,000 impact when a negation dropout turned "may not be used" into "puede utilizarse" (Amavita, RFI Anatomy).

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 **1.3.0**, last updated August 22, 2026. Every substantive change to the ANMAT requirements on this page is recorded below.

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.