LATAM REGULATORY GUIDES · PARAGUAY

DINAVISA Regulatory Translation Requirements: The Complete Guide for Drugs, Devices, and Clinical Trials in Paraguay

Ley 1119/1997 Art. 11, the INF-DI-01 V01 dual-language items, Resolución 056/2026 and ICH E6(R3), plus the DIEE-versus-DINAVISA routing warning.

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Dual-language IB requirement

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Section A. Regulator profile

Name: *Dirección Nacional de Vigilancia Sanitaria* (National Directorate of Sanitary Surveillance), DINAVISA — Paraguay's autonomous health-products regulator. DINAVISA grants sanitary registration for medicines, medical devices, in vitro diagnostics, biologicals and food; issues GMP certifications; runs pharmacovigilance and technovigilance; authorises clinical trials; and accredits ethics committees on the complementary tier (DINAVISA — Historia). Its statutory

predecessor is the DNVS (*Dirección Nacional de Vigilancia Sanitaria*), and both designations circulate in the current legal corpus — resoluciones from 2021 and earlier are still signed *DNVS D.G.* — the two names refer to the same institution across a legal-succession boundary (DINAVISA — Historia).

Establishing statute: DINAVISA was constituted by Ley N° 6788 de 23 de agosto de 2021, which conferred *personería jurídica*, administrative and financial autonomy, autarquía and its own patrimony, relating to the Executive through the *Ministerio de Salud Pública y Bienestar Social* (MSPBS) — but as a legally distinct entity, not an MSPBS office (DINAVISA — Historia). Ley N° 7050 de 4 de enero de 2023 (PGN 2023) consummated DINAVISA's autarchy in budget terms, and Decreto N° 8759 de 26 de enero de 2023 implemented it operationally (DINAVISA — Historia). Ley N° 7361 de octubre de 2024 modified and extended Ley 6788, notably adding food regulation to DINAVISA's remit (Resolución DINAVISA N° 056/2026 preamble). The substantive product statute — the one that makes Spanish a legal requirement and makes trial pre-authorisation compulsory — is Ley N° 1119/1997 de Productos para la Salud y Otros, whose Art. 11 supplies the statutory Spanish mandate and whose Art. 30 supplies the statutory trial-authorisation duty (Ley N° 1119/1997).

Scope: DINAVISA regulates medicines (chemical synthesis, biologicals, biotechnological, biosimilars, homeopathics, herbals), medical devices across four risk classes, in vitro diagnostics, cosmetics, hygiene products, food (from 2024 forward) and other health products — plus the establishments that manufacture, import, distribute and dispense them. Clinical trials in medicinal products, vaccines, medical devices and IVDs sit inside DINAVISA under Resolución DINAVISA N° 238/2024 as amended by Resolución DINAVISA N° 056/2026 (Resolución 238/2024; Resolución 056/2026). Ethics-committee accreditation is split two ways: the basic tier sits with the MSPBS under Resolución S.G. N° 379/2025, and the complementary tier — the one that qualifies a committee to review interventional trials — sits with DINAVISA under Resolución DINAVISA N° 327/2025 (DINAVISA — Dirección de Investigación).

Website: https://dinavisa.gov.py — the consolidated public portal for resoluciones, requisitos, instructivos, communications and public registers. The site advertises *"Documentación VUI 2.0"* — the Ventanilla Única de Importación — and hosts DINAVISApy, the electronic platform for market-authorisation and post-registration filings, authorised by Resolución S.G. N° 254/2021 with implementation timetable in Resolución DNVS D.G. N° 82/2021 (Res S.G. 254/2021; Res DNVS 82/2021).

Printed contact points. DINAVISA publishes multiple institutional inboxes on the current site footer and on desk-specific pages: secretariageneral@dinavisa.gov.py (site-wide), consultas.dinavisa@dinavisa.gov.py (general enquiries), dispositivos.medicos@dinavisa.gov.py (devices), invitro@dinavisa.gov.py (IVDs), biologicos@dinavisa.gov.py (biologicals), sintesis@dinavisa.gov.py (chemical-synthesis drugs), and dgrapa@dinavisa.gov.py (food) (DINAVISA — Contacto). The DINAVISA I building is at Iturbe 883 casi Manuel Domínguez, Asunción, with telephone lines *Atención al Usuario* 0800 111 630, (021) 453 666, (021) 449 944 and (021) 444 274 (DINAVISA — Contacto).

Current head of authority. *Director Nacional (Interino):* MSc. Qco. Fco. Jorge Iliou Silvero, who signs Resolución DINAVISA N° 056/2026 in that capacity (Resolución 056/2026; DINAVISA — Autoridades). The Dirección de Investigación — the operational desk that receives clinical-trial

dossiers — is not publicly attributed to a named head on the current Dirección de Investigación page. We route trial correspondence to that desk without naming an individual.

Adjacent bodies sharing responsibility. Paraguay's architecture is layered, and getting the language rule right depends on which desk a document lands on — and, more importantly, on which desk it does not land on.

Body	Role	Reference
DINAVISA — Dirección de Investigación	Operational hub for clinical-trial authorisation; issues the requisitos guidance (INF-DI series); receives paper-and-foliated trial dossiers; publishes the accredited-committee register; there is no publicly named head	Dirección de Investigación
DINAVISA — Dirección General de Regulación de Productos para la Salud (DGRPS)	Market-authorisation desks for drugs, devices, IVDs, biologicals; issues the ITR/INF-DGRS instructivos; operates DINAVISApy	Resolución DINAVISA N° 226/2024; ITR-DGRS-002
MSPBS — Dirección de Investigaciones y Estudios en Salud (DIEE)	Research-policy office inside the Ministerio de Salud; runs basic-tier CEIS accreditation under Res S.G. N° 379/2025 and the *Política Nacional de Ética en la Investigación*; inbox `diee.dgpe@mspbs.gov.py`	MSPBS — DIEE
Comités de Ética en Investigación (CEIS)	Review protocols; only two currently hold DINAVISA complementary accreditation — the Instituto de Previsión Social CEIS and the Instituto Nacional del Cáncer CEIS	INF-DI-15 Registro de CEIS
Corte Suprema de Justicia — Secretaría General	Enrols and holds the *matrícula* of *traductores públicos matriculados*; the single sworn-translation profession in Paraguay	CSJ — Secretaría General
Ministerio de Relaciones Exteriores — Dirección de Legalizaciones	Issues Paraguay-side apostilles and consular legalisations; hosts the e-Register	HCCH Paraguay e-Register notice

Common confusion — MSPBS DIEE is not the trial desk. *Not routed:* The DIEE inbox `diee.dgpe@mspbs.gov.py` sits inside the Ministerio de Salud's research-policy office, not inside DINAVISA. DIEE administers basic-tier CEIS accreditation and the national research policy; it does not receive, evaluate or authorise clinical-trial dossiers (MSPBS — DIEE; Resolución 238/2024 preamble). Sponsors who mail a CTA package to DIEE lose weeks — DIEE cannot act on it,

DINAVISA has not received it, and the file exists nowhere until it is re-filed on paper at DINAVISA's mesa de entrada.

Common confusion — DINAVISA does not accept trial dossiers by email at all. *Not routed:* The Dirección de Investigación page prints only *"Teléf./Fax: (021) 453 666"* — no inbox — and INF-DI-01 V01 Nota 2 requires the dossier *"en formato impreso y foliado."* No trial submission channel exists at DINAVISA in electronic form. The archived 2023-era address `direccion.investigacion@dinavisa.gov.py` circulates on superseded PDFs but is not printed on any current page; do not treat it as a live inbox. For general institutional enquiries — not trial submissions — the live routes are secretariageneral@dinavisa.gov.py and consultas.dinavisa@dinavisa.gov.py (DINAVISA — Contacto; INF-DI-01 V01).

Two structural facts about DINAVISA trial filings that reshape translation planning. First, the trial channel is paper, not digital. DINAVISApy is real, it is impressive on the market-authorisation side, and it does not touch clinical-trial submissions. INF-DI-01 Nota 2 requires the file *"en formato impreso y foliado"* — printed, foliated, hand-delivered (INF-DI-01 V01). Second, the file must land complete on the first delivery, because per-cycle correction quotas are finite (Section F): drug files have three technical evaluations and then denial (ITR-DGRS-001 V06 Tabla 2 points 9–10); device files see the second-round applicant window halve to 30 working days on introducing new information (Resolución 226/2024 Art. 9). A translation defect discovered at filing is a translation defect that cannot be quietly cured — it consumes a correction cycle, or halves the next one.

Contact points we will not invent. The Dirección de Investigación page prints no email address for the desk. The two accredited CEIS institutions publish generic institutional contact channels but no clinical-trial-specific inbox on their DINAVISA register entries. `[UNVERIFIED — source silent]` on any dedicated CEIS trial-desk mailbox for either the Instituto de Previsión Social or the Instituto Nacional del Cáncer. `[UNVERIFIED — source silent]` on the identity of the current head of the Dirección de Investigación, which is not stated on the Dirección de Investigación page. We route CEIS correspondence through each institution's public research office and DINAVISA correspondence through secretariageneral@dinavisa.gov.py.

Section B. Official language requirements

Paraguay's language rule is layered but converges on a single operative principle: Spanish is the language of decision, use and record — with a mandatory dual-language filing obligation on clinical trials that has no analogue in the rest of the region. Reading only the statute misses the trial-specific dual-language mandate; reading only the instructivos misses the constitutional-level Spanish anchor.

Constitutional anchor — Constitución Nacional Art. 140 (Guaraní and Spanish as official languages). Paraguay's constitution designates both Spanish (*castellano*) and Guaraní as official languages of the Republic, and Ley de Lenguas N° 4251/2010 elaborates that regime. This does not create a Guaraní translation obligation for DINAVISA filings. No DINAVISA instrument reviewed for this guide — Res 238/2024, Res 056/2026, Res 226/2024, Decreto 2479/2024, the INF-DI-

01/INF-DGRS-001/ITR-DGRS-001-002 series, Ley 1119/1997 — requires Guaraní translation of any regulatory document. The affirmative negative is worth stating: DINAVISA operates in Spanish only. Guaraní translation of participant-facing informed consent may be provided as a good-clinical-practice practice where the population warrants it, but is not a DINAVISA filing requirement.

Statutory anchor — Ley N° 1119/1997, Art. 11 (verbatim, product law):

> *"La solicitud de autorización sanitaria de productos farmacéuticos, alimentos dietéticos y dietoterápicos, aguas minerales, cosméticos y peluquería, productos de higiene doméstica, materiales, instrumental o equipamiento para uso médico odontológico, laboratorios de análisis clínicos, u otros productos, procesos o servicios de aplicación en el hombre, sobre los que el Ministerio de Salud Pública y Bienestar Social ejerce vigilancia sanitaria, contendrá los siguientes datos: 1. Solicitud de autorización sanitaria, redactada en español..."*

Source: Ley N° 1119/1997. The statute puts the Spanish drafting mandate at the top of the requirements list. Art. 11.3 goes further: *"la denominación, la fórmula cualitativa y cuantitativa, la forma farmacéutica, y demás textos que integran el registro sanitario, correspondientes a los productos autorizados por el Ministerio de Salud Pública y Bienestar Social,"* meaning that the Spanish texts filed with the application are part of the authorisation itself — not an ancillary translation obligation but a component of the legal instrument that permits sale (Ley N° 1119/1997).

Statutory anchor — Ley N° 1119/1997, Art. 30 (verbatim, trials):

> *"Todo estudio clínico realizado con productos farmacéuticos, cosméticos, dietoterápicos, materiales, instrumental o equipamiento para uso médico u odontológico, requerirá la autorización previa del Ministerio de Salud Pública y Bienestar Social. El Ministerio establecerá las condiciones y requisitos a los que se ajustarán los estudios."*

Source: Ley N° 1119/1997. Pre-authorisation is a statutory obligation, not a reglamento convenience — which is why Resolución 238/2024's requisitos are the enforceable rules, not guidance.

Trial-authorisation anchor — INF-DI-01 V01, Items 1.7 and 1.8 (verbatim, DUAL-LANGUAGE FILING):

> *"1.7. Manual del Investigador (Investigator's Brochure) que incluya los resultados de los estudios no clínicos, en versión en español y en idioma original. […] 1.8. Protocolo del estudio, versión en español y en idioma original."*

Source: INF-DI-01 V01. This is the operative sentence of the Paraguay trial regime and it is decisive: the Investigator's Brochure and the protocol must be filed in complete Spanish AND in the complete original language, in the same paper-and-foliated dossier. There is no source-language-plus-summary pathway. There is no reviewer-discretion carve-out. There is no reliance route that waives it. The IB explicitly *includes* the non-clinical study results — item 1.7 folds preclinical into the IB and pulls it inside the dual-language obligation (INF-DI-01 V01).

Rejection-clause anchor — Resolución DINAVISA N° 056/2026, Art. 2 (verbatim):

> *"El Manual del Investigador deberá cumplir con la Guía ICH E6(R3) de Buenas Prácticas Clínicas y sus requisitos documentales correspondientes. La falta de cumplimiento será causal de rechazo de la solicitud de autorización del ensayo clínico."*

Source: Resolución DINAVISA N° 056/2026. ICH E6(R3) compliance of the IB — *and its documentary requirements* — is a rejection ground. Read together with INF-DI-01 items 1.7–1.8, an incomplete Spanish IB is an incomplete IB, and an incomplete IB is a rejection ground written into the operative resolución.

Devices anchor — Resolución DINAVISA N° 226/2024, Art. 19 (verbatim, devices):

> *"Las instrucciones de uso serán presentadas en idioma español, en su totalidad, sin la posibilidad de una versión parcial."*

Source: Resolución 226/2024. Device IFUs must be filed in Spanish, in full, no partial-translation option. This is a stronger obligation than Panamá's ISO-15223-symbol carve-out or El Salvador's summary-tolerant clause: the entire IFU is a Spanish deliverable, in Paraguay, without negotiation.

Devices anchor — ITR-DGRS-002 V02, Point 6 (sworn translation for device dossiers):

> *"Toda documentación en idioma extranjero, tanto legal como técnica, deberá contar con traducción realizada por Traductor Público matriculado por la Corte Suprema de Justicia."*

Source: ITR-DGRS-002 V02. Devices carry a broader sworn-translation duty than drugs: both legal AND technical foreign documents require Corte Suprema-matriculated *traductor público* certification, with only the ITR-DGRS-002 point 7.1 extract carve-out for voluminous technical manuals (only pages actually used in the DINAVISApy declaration need sworn translation).

Drugs anchor — Decreto N° 2479/2024, Art. 9 (verbatim, drug labelling):

> *"El envase primario y el envase secundario del producto farmacéutico deberán presentar la rotulación en idioma castellano, en caracteres claramente visibles."*

Source: Decreto 2479/2024. Note the term: "castellano," not "español" — the same language, but a term choice that reflects Paraguayan legislative usage and that a translator must preserve when quoting the article. The prospecto and RCP under Resolución 477/2023 are subject to the same Spanish rule with QR-code delivery permitted (Res 477/2023).

Three doctrinal facts embedded in the framework. First, Paraguay's clinical-trial regime is the outlier for LATAM: unlike Panamá's English-with-Spanish-summary statutory carve-out for study evidence, unlike El Salvador's defensible narrow-scope preclinical posture, unlike Ecuador's ARCSA English-tolerance for technical annexes, Paraguay requires full bilingual IB and protocol filing by explicit written decree, with rejection as the stated consequence of non-compliance. Second, over-labelling is permitted for imported drug packs but not for the prospecto: an imported drug pack may carry over-labelled Spanish text to complete rotulación under Decreto 2479/2024, but the prospecto/RCP must be filed and printed in Spanish from origin — no sticker remedy on the leaflet (INF-DGRS-001 V05; Res 477/2023). Third, devices allow no relabelling, no over-labelling, no partial IFU: Art. 19 of Res 226/2024 is written specifically to close the carve-outs other regulators leave open.

Document-by-document language table (drugs — ITR-DGRS-001 V06, INF-DGRS-001 V05, Decreto 2479/2024; devices — Res 226/2024, ITR-DGRS-002 V02; trials — Res 238/2024, Res 056/2026, INF-DI-01 V01).

Document	Language rule	Statutory anchor
Application form (drugs, devices, trials)	Spanish, drafted from origin	Ley 1119/1997 Art. 11.1

Document	Language rule	Statutory anchor
Investigator's Brochure (trials)	Complete Spanish AND complete original language — dual-language filing	INF-DI-01 V01 item 1.7
Clinical protocol (trials)	Complete Spanish AND complete original language — dual-language filing	INF-DI-01 V01 item 1.8
Non-clinical / preclinical evidence (trials)	Included inside the IB; therefore dual-language	INF-DI-01 V01 item 1.7
Informed consent form (trials)	Spanish, CEIS-approved, initialled by CEIS	INF-DI-01 V01 item 1.9
CEIS approval and correspondence (trials)	Spanish, from the CEIS	INF-DI-01 V01 items 1.4–1.5
Package artwork (trials, drugs)	Spanish (*castellano*)	INF-DI-01 V01 item 1.13; Decreto 2479/2024 Art. 9
ICH E6(R3) documentary requirements (trials)	Spanish, per Art. 2 rejection clause	Resolución 056/2026 Art. 2
Foreign legal documents (all categories)	Sworn Spanish by *traductor público matriculado*; apostille/consular legalisation	INF-DI-01 V01 Nota 4; ITR-DGRS-002 point 6
Foreign technical documents — devices	Sworn Spanish (broader than drugs)	ITR-DGRS-002 point 6
Voluminous device technical manuals	Sworn Spanish of pages used in DINAVISApy declaration only	ITR-DGRS-002 point 7.1
Foreign technical documents — drugs	Translation "en los casos necesarios" — reviewer discretion	ITR-DGRS-001 V06 point 6
Device IFU / insert	Full Spanish, no partial version	Resolución 226/2024 Art. 19
Device labels	Spanish; combinations permitted with Spanish present; no relabelling on primary use	Resolución 226/2024 Arts. 19–20
Tecnovigilancia legend on device labels	Verbatim Spanish statutory legend	Resolución 226/2024 Art. 20
Drug prospecto / RCP	Spanish, filed from origin; QR-code delivery permitted	Resolución 477/2023; Decreto 2479/2024
Drug primary and secondary rotulación	Castellano, clearly visible characters	Decreto 2479/2024 Art. 9
Imported drug pack — over-labelling	Permitted to complete Spanish rotulación	INF-DGRS-001 V05

Document	Language rule	Statutory anchor
Imported drug pack — prospecto	Not subject to the over-labelling carve-out; must ship in Spanish	Resolución 477/2023
CoA — drugs	Foreign-language accepted with reviewer-discretion translation	ITR-DGRS-001 V06
CLV / CPP / CFS foreign legal instruments	Sworn Spanish + apostille	Ley 1119/1997 Art. 11; ITR-DGRS-002 point 6
GMP certificate	Sworn Spanish + apostille	ITR-DGRS-001 V06; Decreto 2479/2024
Contracts, poderes, statutes	Sworn Spanish + apostille	ITR-DGRS-002 point 6
Adenda to contracts	*Certificación de firmas* required; sworn Spanish if foreign	ITR-DGRS-001 V06
Progress and final trial reports	Spanish, structured per ICH E3 (056/2026 Art. 3)	Resolución 056/2026 Art. 3
SUSAR / RAMSI reports	Spanish	INF-DI-11 cronograma

Mercosur harmonisation overlay. Paraguay adopts several Mercosur GMC resolutions by decree — GMC 20/2011, 50/1998, 72/1998, 75/2000 are cited in the medicines resoluciones on the DINAVISA site — but Mercosur does not create a horizontal foreign-language exception. Mercosur harmonises technical dossier content; language remains a national attribution, and Paraguay attributes it to Spanish.

Physical filing point. DINAVISA I, Iturbe 883 casi Manuel Domínguez, Asunción, mesa de entrada. Paper. Foliated. Bound. Signed. That is the filing surface — and the reason Amavita's Paraguay engagements are scoped around physical-file assembly, not electronic-portal upload (DINAVISA — Contacto).

Section C. Sworn vs certified vs simple translation

**Paraguay recognises exactly one sworn-translation category: the* traductor público matriculado *enrolled with the* Corte Suprema de Justicia.* There is no ATA-equivalent professional certification pathway, no notarised sponsor-declaration substitute, no MEDUCA-style ministerial licence. The regime is judicial-branch, per-language-pair, and administered centrally.

Governing instruments.

- Ley N° 879 de 2 de diciembre de 1981 (Código de Organización Judicial), Art. 173 — establishes *traductor público* as an auxiliary of justice enrolled by the Corte Suprema (Ley 879/1981 — MEF text; PJ 2024 concordado edition).

- Acordada de la Corte Suprema de Justicia N° 50 de 7 de mayo de 1997 — reglamenta la matriculación y actuación de los traductores públicos (CSJ Acordada N° 50).
- Secretaría General de la Corte Suprema de Justicia — administers the matrícula, receives filings, issues *constancias de matriculación* on request (CSJ Secretaría General).

Tier table.

Tier	Paraguayan designation	When it applies	Who certifies
Sworn / official	*Traducción por Traductor Público matriculado por la Corte Suprema de Justicia*	Foreign legal documents in any DINAVISA file (drug, device, IVD, biological, trial); foreign technical documents in device files (ITR-DGRS-002 point 6); the IB and protocol Spanish versions in trial files as the language-of-record deliverable (INF-DI-01 V01 items 1.7–1.8)	*Traductor público matriculado*, Corte Suprema, per language pair
Certified	*No expressly recognised category in Paraguay.* No instrument names a supplier or sponsor certification as sufficient. Do not scope for this tier	—	
Simple	*Traducción al español* for technical drug documents "en los casos necesarios" — reviewer-discretion category	Sponsor / CRO — used only where the drug instructivo explicitly permits it, never as a substitute for sworn translation	

The commercially decisive line is the *second row's absence*. Panamá lets a sponsor certify a supplier declaration on a GMP certificate; El Salvador tolerates a certified in-house translation on some technical annexes; Ecuador routinely accepts an unsworn Spanish executive summary. Paraguay does not. Where the instructivo names a translation obligation, it names a *traductor público matriculado*. Where it is silent, the sponsor is guessing against a rejection-clause regime — and guessing against three-strike drug files and 30/60-working-day device windows.

Formal requirements — the per-page and foliation rules. Acordada N° 50/1997 and the ITR-DGRS-002 V02 points 11–12 impose formal requirements that translators — and the sponsors managing them — must supervise:

1. Per-page signature or foliation with stated total page count. Each translated page carries the traductor público's signature and seal, or the file is foliated with the total page count explicitly stated on the translator's certification.

2. Source + translation + apostille bundled in a single file. The English original, the Spanish translation, and the apostille certificate ride together as one bound instrument.
3. The apostille itself is translated. The apostille certificate is a foreign public document; its seals, stamps and marginal annotations are Spanish deliverables.
4. Corporate names, addresses and identifiers travel verbatim. ITR-DGRS-002 point 4 requires platform-declared data to match the attachments; helpful transliteration of a foreign corporate name in the sworn translation produces a mismatch against the CLV, GMP or ISO 13485 certificate — which is a rejection ground on its face. This is a locked-glossary discipline, not a translation judgement.

Three practical consequences of the* traductor público matriculado *regime. First, per language pair: an English→Spanish TPM cannot swear a German→Spanish or Japanese→Spanish translation. A dossier holding a German notified-body certificate, a French sterilisation validation and a Chinese CoA needs three matriculated professionals — not one, not a vendor. Second, Paraguay-matriculated only: a Spanish* traductor jurado*, a US ATA-certified translator, a Colombian* traductor oficial *or an Argentine* traductor público *are not substitutable. The Corte Suprema's matrícula is the only qualifying credential. Third, the profession is not large. Amavita cannot publish a translator count — the public roster URL `https://datos.csj.gov.py/data/traductores` returns HTTP 404 during this research pass, and no other complete matriculado list is published online — but the operational reality is a finite pool of TPM professionals fluent in ISO 10993 biocompatibility language, IEC 60601 electrical-safety terminology, ICH E3 clinical-report structure and ICH E6(R3) IB anatomy. Paraguay-side sworn translation is a queue, not a service on demand.

Apostille sequencing. Paraguay acceded to the Hague Convention with entry into force 30 August 2014, with a Germany carve-out that ran until 6 January 2022 (Germany initially objected under Art. 12 and later withdrew the objection) (HCCH Apostille status table; HCCH Paraguay accession notice; HCCH Germany notifications). The Ministerio de Relaciones Exteriores' Dirección de Legalizaciones is the competent authority; the e-Register is operational (HCCH Paraguay e-Register notice). INF-DI-01 V01 Nota 4 requires apostille or consular legalisation for legal foreign documents, and where the country of origin is not a Hague party, the document travels the consular route.

`[Primary source unavailable]` — the MRE Dirección de Legalizaciones' procedural page at `https://www.mre.gov.py/index.php/tramites/legalizaciones` returned HTTP 403 to automated requests during this research; procedural detail must be re-verified at the counter or by direct enquiry to the MRE.

The sequencing rule. Obtain the signed original abroad; apostille it in the country of origin (or route through the Paraguayan consulate for non-Hague origins); *then* have the Paraguay-matriculated TPM translate the document including the apostille certificate itself and every seal, stamp and marginal annotation; then bundle source + translation + apostille as a single instrument with per-page signature or a foliation certification stating total page count; then file. Translate first and apostille second, and the apostille attaches to a document the TPM never saw while the Spanish version omits the apostille text — the file does not reconcile and the translation is re-done at the sponsor's cost.

The scheduling constraint nobody budgets for. TPM capacity in Paraguay is finite; the population of matriculated English→Spanish translators fluent in ICH E6(R3) IB anatomy, ISO 10993 biocompatibility endpoints, IEC 60601 electrical-safety terminology, sterilisation-validation vocabulary (ISO 11135 / 11137 / 17665) and ICH E3 clinical-report structure is not large. Paraguay's dual-language IB and protocol obligation multiplies the page volume through the TPM channel by roughly two — the file needs the Spanish and the original, and the original stays in original language — which means every project has effectively double the sworn-translation surface of an equivalent Panamá or El Salvador file. Sworn translation in Paraguay is not merely a line item; it is a bottleneck, and the file has to be built to feed the bottleneck, not to fight it.

Amavita's 7th QC gate — Document Currency. Paraguay's currency risk is not on the certificate side — GMP is treated in the ordinary way — but on the *instrument* side. Paraguay rebuilt its trial regime (Res 323/2023 → Res 238/2024 → Res 056/2026), its device regime (Res 226/2024, ITR-DGRS-002), its drug regime (Res 147/2025, 148/2025, 151/2025, ITR-DGRS-001 V06, INF-DGRS-001 V05, Decreto 2479/2024) and its ethics-accreditation regime (Res S.G. 379/2025, Res DINAVISA 327/2025) between 2023 and mid-2026. FOR-VN forms are now FOR-DI forms; INF-DI-01 V01 supersedes V00 which superseded the 2023 requisitos. Anyone working from a pre-2024 Paraguay checklist is working from a dead document. Amavita Sciences™ therefore treats Paraguay as a mandatory 7th-gate jurisdiction: every deliverable is re-checked against the live instrument list before release, every foreign document is timestamped at apostille, at translation and at filing, and a refreshed apostilled original triggers a fresh sworn translation within 48 hours under our First-Pass Acceptance Program.

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

A preclinical package for a single drug or device program routinely runs 800–3,500 pages: pharmacology, PK/ADME, toxicology, safety pharmacology, biocompatibility, electrical safety, sterilisation validation, and their appendices. Every other guide in Amavita's LATAM library — Panamá, El Salvador, Ecuador, Colombia — argues in this section that a well-built Spanish evidence layer discharges most of the translation obligation and preserves English report bodies as technical evidence. Paraguay is the outlier. Paraguay's Dirección de Investigación does not accept a Spanish summary as a substitute for a Spanish IB; the IB is a Spanish deliverable in full, filed in parallel with the original-language IB. This section states that inversion plainly, because scoping a Paraguay engagement against the LATAM norm produces an under-scoped project that fails at filing.

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

For clinical trial authorisation — yes, in full, in Spanish AND in the original language.

The IB carries the non-clinical evidence, and the IB is a dual-language filing.

- INF-DI-01 V01 item 1.7 requires the *"Manual del Investigador (Investigator's Brochure) que incluya los resultados de los estudios no clínicos, en versión en español y en idioma original."* Two things happen in that sentence. First, non-clinical results are folded *inside* the IB — item 1.7 is the successor to the 2023 requisitos' standalone "Estudios preclínicos" item, which Resolución 238/2024 abrogated. Second, the IB — including its non-clinical section — must be filed in complete Spanish and complete original.
- INF-DI-01 V01 item 1.8 repeats the pattern for the protocol: *"versión en español y en idioma original."*
- Resolución 056/2026 Art. 2 makes ICH E6(R3) compliance of the IB — and its documentary requirements — a rejection ground: *"La falta de cumplimiento será causal de rechazo de la solicitud de autorización del ensayo clínico."*

There is no *"en los casos necesarios"* qualifier on item 1.7. There is no reviewer-discretion carve-out. There is no summary pathway. There is no reliance decree that waives the dual-language obligation for foreign-approved products. The whole IB — pharmacology, toxicology, PK/ADME, biocompatibility if applicable, safety pharmacology, all appendices bearing on safety — is a Spanish translation deliverable, and the whole IB is also preserved in the original language in the same paper file. The dual-language obligation is not a redundancy; it is the language-of-record architecture Paraguay has explicitly chosen.

For market-access sanitary registration — mixed, per document class, and different for drugs and devices.

The drug and device regimes attribute translation differently. Drugs: legal instruments — poderes, contratos, CLV, CPP, GMP — always sworn Spanish; technical documentation "en los casos necesarios" per ITR-DGRS-001 V06, which is reviewer discretion; prospecto and RCP Spanish from origin; primary and secondary packaging *castellano* per Decreto 2479/2024 Art. 9. Devices: both legal AND technical foreign documents require sworn translation per ITR-DGRS-002 point 6; the extract carve-out at point 7.1 limits voluminous technical manuals to the pages actually used in the DINAVISApy declaration; IFU full Spanish, no partial version, per Resolución 226/2024 Art. 19. Market-access preclinical is therefore less punishing than trial-stage preclinical for drugs and roughly comparable for devices — but never dispensed with entirely.

The reliance route does not rescue the translation obligation. Paraguay's reliance framework — Ley N° 3283/2007 as extended by Ley N° 7256/2024, referenced by Resolución DINAVISA N° 192/2025 and Resolución DINAVISA N° 182/2026 — permits abbreviated procedures for drugs registered by strict regulatory authorities. It does not waive the Spanish label, prospecto, RCP or sworn-translation requirements. And on the trial side, no reliance decree exists at all — Resolución 238/2024 makes no mention of foreign-approval-based waiver of the IB or protocol dual-language obligation.

D.2 If translation IS required — is it text-only or does it require desktop publishing (DTP)?

Paraguay requires format-faithful Spanish where the underlying document has structure — and in most Paraguay deliverables, it does.

Every version is re-translated. This is the operational point sponsors most often underestimate. Under the dual-language IB and protocol regime, a protocol amendment cycle is not "translate the delta and file"; it is *"re-translate the complete Spanish IB or protocol at the amended version, re-file both languages in parallel, re-secure CEIS approval on the Spanish, and re-foliate the paper bundle."* Substantial amendments have a 15 working-day DINAVISA authorisation clock (INF-DI-11 cronograma; Resolución 238/2024), which is faster than a conventional TPM sworn-translation cycle on a full IB. The amendment stream is where dual-language filing bites hardest, and it is why Paraguay engagements have to be scoped around a delta-translation discipline that can turn a full Spanish IB revision inside a 15-working-day window.

Document class	Translation scope	DTP (visual replication) required?
Investigator's Brochure (trials)	Full Spanish + full original, dual-language (INF-DI-01 V01 item 1.7)	Yes — tables, cross-references and safety-pharmacology tabulations survive; ICH E6(R3) format compliance is a rejection-graded standard (Res 056/2026 Art. 2)
Clinical protocol (trials)	Full Spanish + full original, dual-language (INF-DI-01 V01 item 1.8)	Yes — schedule of assessments, dosing tables, statistical section
Informed consent form (trials)	Spanish, plain readable	Yes — mirror CEIS-approved template with per-page initialling
Package artwork (trials)	Spanish, IB-consistent product identification	Yes — print-ready
Foreign legal documents (all categories)	Sworn Spanish + apostille	Yes — mirror seals, signature blocks, page numbering
Foreign technical documents — devices	Sworn Spanish; extract carve-out for voluminous manuals (ITR-DGRS-002 point 7.1)	Yes where the source has structure
Foreign technical documents — drugs	Translation "en los casos necesarios" — reviewer discretion	Text-flow where used
Device IFU	Full Spanish, no partial version (Res 226/2024 Art. 19)	Yes — regulatory DTP
Device labels + tecnovigilancia legend	Spanish, verbatim statutory legend	Yes
Drug prospecto / RCP	Spanish, QR-deliverable, no over-labelling remedy	Yes
Drug primary/secondary packaging rotulación	*Castellano* (Decreto 2479/2024 Art. 9)	Yes — over-labelling permitted on imported packs, not on the prospecto
Progress and final trial reports	Spanish, structured per ICH E3 (Res 056/2026 Art. 3)	Yes — ICH E3 anatomy

Document class	Translation scope	DTP (visual replication) required?
Contracts / adenda	Sworn Spanish; *certificación de firmas* on adenda	Text-flow where narrative; format-mirror on structured contracts

The rule we apply: if the document has *any* internal structure — a table, a schedule, a signature block, a header hierarchy, a cross-reference — the Spanish deliverable is a DTP deliverable. Linear text dumps are fatal in Paraguay for the same reason they are fatal everywhere else, and additionally because the dual-language file has to survive a foliation and per-page signature discipline that a broken table cannot survive.

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

For the clinical-trial pathway, translation is required for the IB and protocol regardless — there is no substitute. The market-access side has narrower substitution pockets and Amavita builds them where Paraguay's instructivos are explicit. The three-component architecture Amavita uses in Panamá, El Salvador and Ecuador — Spanish executive summary per report, consolidated Spanish technical summary, English originals with Spanish concordance — is *not* deployable as a substitute for the trial-stage IB Spanish translation in Paraguay. It is deployable as a supporting layer alongside the dual-language IB, to give the reviewer a navigable Spanish spine into the non-clinical evidence body, but it does not reduce the sworn-translation surface.

Where the substitution does apply — market-access drugs, non-legal technical documents. ITR-DGRS-001 V06 uses the phrase *"traducción en los casos necesarios"* for non-legal technical documents — a reviewer-discretion category. Amavita treats this as a pocket of controlled Spanish provision: proactively deliver an executive summary in Spanish for each major technical report; keep the English body indexed against the summary; and route the summary through a matriculated TPM only where the reviewer requests sworn certification. This compresses the sworn-translation surface on the drug market-access side without inviting a summary-insufficiency defect.

Where the substitution does not apply. Devices under ITR-DGRS-002 point 6 do not tolerate a summary substitute for legal *or* technical foreign documents — the only carve-out is the point 7.1 extract rule for voluminous manuals. Trials under INF-DI-01 items 1.7–1.8 do not tolerate any substitute for the dual-language IB and protocol.

D.4 Consolidated preclinical instruction table

Preclinical document	— dual-language mandatory	mixed	— sworn-broad
ISO 10993 biocompatibility reports	Full Spanish inside the IB + full original inside the IB (INF-DI-01 V01 item 1.7)	Not typically a drug document	Sworn Spanish; extract carve-out (ITR-DGRS-002 points 6, 7.1)

Preclinical document	— dual-language mandatory	mixed	— sworn-broad
IEC 60601 electrical-safety test reports	If a device trial: full Spanish inside IB + original	Not applicable	Sworn Spanish; extract carve-out
Sterilisation validation (ISO 11135 / 11137 / 17665)	Full Spanish inside IB + original	Sworn Spanish where filed	Sworn Spanish; extract carve-out
GLP animal / toxicology study reports	Full Spanish inside IB + original	Reviewer discretion "en los casos necesarios" (ITR-DGRS-001 V06)	Sworn where filed
Biologicals preclinical-phase information	Full Spanish inside IB + original	Sworn Spanish per Res 233/2024 family (biologics page)	Not typically a device document
CB Test Certificates / notified-body certificates	Full Spanish + original inside IB annexes	Not typically a drug document	Sworn Spanish (legal instrument under ITR-DGRS-002 point 6)
Clinical study reports	Carried inside the IB; dual-language	Sworn Spanish where filed	Sworn Spanish where filed
Certificado de análisis	Sworn Spanish where filed as IMP CoA	Foreign accepted with reviewer-discretion translation	Sworn Spanish
Investigator's Brochure	Full Spanish + full original — non-negotiable	Not a market-access document	Not a market-access document
Clinical protocol	Full Spanish + full original — non-negotiable	Not a market-access document	Not a market-access document
Informed consent form	Spanish, CEIS-approved	Not a market-access document	Not a market-access document
CPP / CLV / CFS	Sworn Spanish + apostille	Sworn Spanish + apostille	Sworn Spanish + apostille
GMP certificate / QP declaration	Sworn Spanish + apostille	Sworn Spanish + apostille	Sworn Spanish + apostille
Powers of attorney, contracts	Sworn Spanish + apostille	Sworn Spanish + apostille	Sworn Spanish + apostille
Device IFU	Not applicable pre-authorisation	Not applicable	Full Spanish, no partial version (Res 226/2024 Art. 19)

Preclinical document	— dual-language mandatory	mixed	— sworn-broad
Labels and cartons	Spanish + product identification	*Castellano* + no prospecto over-labelling (Decreto 2479/2024 Art. 9)	Spanish; combinations permitted; tecnovigilancia legend verbatim
Catalogues (devices)	Not applicable	Not applicable	Extract carve-out available (ITR-DGRS-002 point 7.1)
Progress / final trial reports	Spanish per ICH E3 (Res 056/2026 Art. 3)	Not applicable	Not applicable
SUSAR / RAMSI safety reports	Spanish, 10 días corridos	Sponsor pharmacovigilance channel	Tecnovigilancia channel

D.5 Where the preclinical translation risk actually sits

The clinical-trial pathway carries the highest translation-scope risk in Latin America, and the risk is textual — not anecdotal, not reviewer-discretion. Paraguay is the single country in Amavita's LATAM library where the answer to "do we have to translate the whole IB into Spanish" is unqualified *yes*, and where non-compliance is written into a resolución as *"causal de rechazo de la solicitud de autorización del ensayo clínico"* (Resolución 056/2026 Art. 2). The other guides in this series argue against over-translating; the Paraguay guide argues against under-translating.

Full bilingual filing (Spanish AND original language) is mandatory for the IB and protocol per INF-DI-01 V01 items 1.7 and 1.8. Non-compliance is an explicit rejection ground per Resolución DINAVISA N° 056/2026 Art. 2, which makes ICH E6(R3) compliance of the IB and its documentary requirements a *causal de rechazo*. There is no summary substitute, no reliance decree, no reviewer-discretion pocket, no "we'll get you an amendment" recovery. The Spanish IB is filed complete on day one, or the file is rejected.

Beyond that structural inversion, five failure modes, in descending order of realised cost:

1. The Spanish IB being incomplete. A partial Spanish translation — safety pharmacology in Spanish, non-clinical PK still English — is not a defensible position under INF-DI-01 item 1.7. The item requires *"que incluya los resultados de los estudios no clínicos, en versión en español y en idioma original"* — the non-clinical results are inside the IB, and the IB is dual-language. Filing an incomplete Spanish IB consumes one of the drug-file's three technical evaluation rounds (ITR-DGRS-001 V06 Tabla 2 point 9; Res 226/2024 Art. 9 analog for devices).
2. Amendment-cycle collapse. Resolución 238/2024 Art. 51-52 substantial-amendment clock runs at 15 working days on the DINAVISA side; the sponsor has 30 working days to cure objections. A full re-translated Spanish IB does not turn inside a 30-working-day window if the

TPM pipeline is not pre-positioned. This is where dual-language filing turns amendments from a cost line into a schedule-breaking risk.

3. Version drift between Spanish and original. The dual-language file is not two independent files — it is one instrument in two languages, and both must be at the same version at the same time. A late Spanish revision that is not mirrored in the filed original, or an errata to the original that is not carried into Spanish, is a version-parity defect on its face.
4. Corporate name and address transliteration. ITR-DGRS-002 point 4 requires platform-declared data to match attachments. Sworn translators who "helpfully" transliterate a foreign corporate name in the Spanish IB create a mismatch against the CLV, GMP or ISO 13485 certificate that a reviewer catches on the first read. Locked-glossary discipline: corporate names, addresses, certificate identifiers travel verbatim, unlocalised.
5. Foliation and per-page signature failure. ITR-DGRS-002 point 11 and Acordada N° 50/1997 require per-page signature or foliation with stated total page count. A translated deliverable that arrives without one is not a filable Spanish version — it is a text file the mesa de entrada cannot accept.

Section D bottom line — the inversion. In Panamá, El Salvador, Ecuador, Colombia and most of LATAM, Amavita's message on preclinical translation is *"you do not have to translate as much as you think — here is how we prove it."* In Paraguay, the message is the opposite: you have to translate the whole IB into Spanish, and you have to file the whole original alongside it, and DINAVISA will reject you if you do not, and there is no cheaper way to do it that we would recommend to a client. The value we add in Paraguay is not compression of translation volume; it is execution discipline — dual-language version control, matriculated-TPM throughput management, apostille sequencing, foliation compliance, and pre-positioned amendment-cycle capacity — inside a rejection-clause regime where the file has to be right on the first delivery.

CATEGORY 1: DRUGS

D1. Drug market access — DINAVISA pathway

Governing instruments.

- Ley N° 1119 de 3 de septiembre de 1997 — *Ley de Productos para la Salud y Otros*; substantive product law. Art. 11 sets the Spanish drafting mandate; Art. 30 sets the trial pre-authorisation duty (Ley 1119/1997).
- Decreto N° 2479 de noviembre de 2024 — requirements for issuance and renewal of the *registro sanitario*; Art. 9 sets the primary and secondary rotulación in *castellano* (Decreto 2479/2024).
- Resolución DINAVISA N° 147/2025 — *procedimiento ordinario* for sanitary registration of medicines (Res 147/2025).

- Resolución DINAVISA N° 148/2025 — *procedimiento abreviado* for essential medicines (Res 148/2025). Note the number: this is the drug Res 148/2025 — distinct from the device Res 148/2024 (device authority list), one year apart.
- Resolución DINAVISA N° 151/2025 — post-registration modifications (Res 151/2025).
- ITR-DGRS-001 V06 (20 May 2026) — current drug registration instructivo; three-evaluation limit, 90/60 working-day applicant response clocks, sworn-translation scope for legal instruments (ITR-DGRS-001 V06).
- INF-DGRS-001 V05 (1 Jun 2026) — current ordinary-procedure requirement list; artwork and prospecto Spanish clauses, over-labelling carve-out for imported drug packs, electronic-verification apostille waiver, CTD acceptance (INF-DGRS-001 V05).
- Resolución DINAVISA N° 477/2023 — QR-code prospecto guidelines (Res 477/2023).
- Ley N° 3283/2007 as extended by Ley N° 7256/2024 — reference-country classification; Resolución DINAVISA N° 192/2025 (strict regulatory authority list); Resolución DINAVISA N° 182/2026 (country classification) (Ley 7256/2024).

Registration modalities.

Modality	When it applies	Reference
Procedimiento ordinario	Full technical evaluation route; new products without a qualifying foreign registration; requisitos per INF-DGRS-001 V05	Res 147/2025; ITR-DGRS-001 V06
Procedimiento abreviado (esencial)	Essential medicines route; compressed requisitos; abbreviated evaluation	Res 148/2025; INF-DGRS-006 (companion requirement list)
Reference-country reliance	Products registered by strict regulatory authority per Res 192/2025 / 182/2026	Ley 3283/2007 + Ley 7256/2024
Registro sanitario condicional	Conditional registration under Res 338/2022	Res 338/2022
Post-registration modifications	Res 151/2025	Res 151/2025

Language and translation stack — drugs.

- **Product labelling and rotulación:* castellano*, clearly visible characters, on primary and secondary packaging** (Decreto 2479/2024 Art. 9).
- Over-labelling permitted on imported drug packs to complete Spanish rotulación (INF-DGRS-001 V05) — one of the very few over-labelling permissions in the Paraguay corpus.
- Prospecto / RCP: Spanish from origin, no over-labelling remedy, QR-code delivery permitted per Res 477/2023. Ley 1119/1997 Art. 11.3 makes the prospecto text part of the authorisation itself.

- CLV / CPP / GMP certificate: sworn Spanish + apostille, bundled with translation and apostille in a single instrument (ITR-DGRS-002 point 12 discipline applied to drugs; ITR-DGRS-001 V06).
- Fórmula cuali-cuantitativa: Spanish, tabular structure preserved.
- Powers of attorney, contracts, adenda: sworn Spanish + apostille; adenda require *certificación de firmas*; contracts must specify each party's functions.
- Technical documentation: sworn Spanish "en los casos necesarios" — reviewer discretion (ITR-DGRS-001 V06).
- CoA: foreign-language accepted with reviewer-discretion Spanish translation.
- Manufacturer address: exactly as declared in the reference-country GMP (ITR-DGRS-001 V06 point 4). No paraphrasing.

Fees. [Primary source note: the fee scale is set annually in DINAVISA's *aranceles* resolución, indexed to the jornal mínimo. Do not quote a Guaraní figure without checking the current arancel. The 2026-2027 arancel is published at [ARANCELES DINAVISA 2026-2027] (https://dinavisa.gov.py/wp-content/uploads/2026/07/ARANCELES-DINAVISA-2026-2027.pdf).]

Reliance / recognition. Paraguay operates a reference-country classification under Ley 3283/2007 as extended by Ley 7256/2024, with the strict regulatory authority list at Res 192/2025 and country classification at Res 182/2026. The abbreviated procedure at Res 148/2025 is the operative reliance-adjacent route for essential medicines. None of the reliance instruments waive the Spanish rotulación, prospecto, RCP, sworn-translation of legal instruments, or Ley 1119/1997 Art. 11 language obligations.

D2. Drug regulatory submissions

Base dossier per INF-DGRS-001 V05, with the language status of each item.

1. Solicitud de autorización sanitaria — Spanish, per Ley 1119/1997 Art. 11.1
2. Power of attorney to a Paraguay-resident representative — sworn Spanish + apostille if foreign
3. CLV / CPP — apostilled; sworn Spanish annexed
4. GMP certificate — sworn Spanish + apostille; declared manufacturer address exactly as in GMP
5. Fórmula cuali-cuantitativa — Spanish, tabular preservation
6. Monograph — Spanish or accepted pharmacopoeial reference
7. Analytical methods — validation records
8. Finished-product specifications
9. Labels and rotulación per Decreto 2479/2024 — Spanish artwork, print-ready; over-labelling allowed on imported packs
10. Prospecto / RCP — Spanish from origin; QR-code delivery permitted per Res 477/2023
11. Stability-study report

12. Safety and efficacy studies — sworn Spanish "en los casos necesarios"
13. CoA — foreign or Spanish; reviewer discretion on translation
14. Fee per current arancel resolución

Applicant response clocks. ITR-DGRS-001 V06 Tabla 2 points 9–10: 90 working days from notification to cure observations; 60 working-day extension available only in exceptional and justified cases, requested through mesa de entrada. Maximum three technical evaluations. Failure to cure by the third denies the application. This is the arithmetic that turns translation quality from a professionalism argument into a countdown.

Post-registration modifications. Res 151/2025 governs post-approval change; adenda require *certificación de firmas*; contracts must specify each party's functions.

Pharmacovigilance obligations. Paraguay's pharmacovigilance regime attaches to the registration holder; ADR reporting, PSUR periodicity and SUSAR channels are set by DINAVISA's pharmacovigilance instruments. [Primary source note: article-level PSUR-language clauses were not extracted from resoluciones during this research pass; do not attribute a specific PSUR language rule to Res 233/2024 or the 215/2025 family without a fresh verification pass.]

D3. Drug clinical trials

Governing stack. Ley 1119/1997 Art. 30 + Resolución DINAVISA N° 238/2024 + Resolución DINAVISA N° 056/2026 + INF-DI-01 V01. Ethics-committee accreditation splits between MSPBS basic (Res S.G. 379/2025) and DINAVISA complementary (Res 327/2025).

Ethics review. Interventional trials require review by a CEIS holding DINAVISA complementary accreditation. Currently only two institutions are DINAVISA-accredited: the Instituto de Previsión Social CEIS and the Instituto Nacional del Cáncer CEIS (INF-DI-15 register). This is a national capacity constraint sponsors must plan around — two committees for the entire country, which produces predictable queue behaviour.

DINAVISA authorisation. INF-DI-11 cronograma: 60 working days to authorise, deny or object; 15 working days for accelerated authorisation in a declared public-health emergency (Res 238/2024 Art. 51) or MEURI (Art. 52); 15 working days for substantial amendments; 30 working days applicant response to objections; 60 working days for progress and final reports; 30 working days for site-inspection reports.

Trial dossier per INF-DI-01 V01, 17 items with translation load flagged.

1. Application, presented in Spanish
2. Sponsor institutional documentation
3. Principal investigator credentials
4. CEIS approval (Spanish)
5. Ethics correspondence (Spanish)

6. Insurance / coverage
7. Investigator's Brochure — full Spanish AND full original language, ICH E6(R3) compliant — includes non-clinical results
8. Protocol — full Spanish AND full original language
9. Informed consent form — Spanish, CEIS-approved, per-page initialled
10. Declaración jurada de BPM (FOR-DI-33) — new in V01
11. Sponsor certifications
12. Study-site declarations
13. Package artwork in Spanish
14. WHO ICTRP registration
15. Manufacturer / IMP documentation
16. Signed compromiso de archivo (10-year retention obligation)
17. Fee per current arancel

Nota 2: *"formato impreso y foliado"* — paper, foliated, bound. Nota 4: apostille or consular legalisation for legal foreign documents. The trial channel is paper.

Trial-startup translation package, minimally scoped for Paraguay.

Deliverable	Language	Sworn?	DTP?
Protocol + synopsis	Full Spanish + full original	Yes — TPM matriculado	Yes
Informed consent + assent	Spanish, CEIS-approved	Sworn if legal instrument context; readability-graded	Yes
Investigator's Brochure	Full Spanish + full original, including non-clinical results	Yes — TPM matriculado	Yes
Preclinical reports inside the IB	Inside the IB — full Spanish + full original	Yes	Yes
Package artwork	Spanish	Yes if artwork DTP required	Yes
CEIS approval	Spanish, from CEIS	No	No
Insurance / coverage documentation	Spanish; sworn if foreign	Yes	No
Sponsor authorisations, POAs	Sworn Spanish + apostille	Yes	No
GMP certificate / QP declaration	Sworn Spanish + apostille	Yes	No

Deliverable	Language	Sworn?	DTP?
Progress reports	Spanish, per ICH E3 for final	No	Yes for final
SUSAR / RAMSI	Spanish, 10 días corridos	No	No

CATEGORY 2: MEDICAL DEVICES

E1. Device market access — DINAVISA pathway

Governing instruments.

- Resolución DINAVISA N° 226/2024 (August 2024) — the current device framework. Art. 6 requirements; Art. 7 NSO nullity; Art. 8 simplified process (reliance); Art. 9 timelines (45/120 working-day evaluation; 60/30 working-day applicant response); Arts. 10–12 ten-year validity and renewal; Art. 13 post-authorisation modifications; Art. 14 modification timelines; Art. 19 Spanish IFU, full, no partial version; Art. 20 tecnovigilancia legend; Art. 22 combination devices; Art. 23 families/systems/kits; Art. 25 condition of sale; implant-card provisions; Anexos I–V (Res 226/2024).
- ITR-DGRS-002 V02 (9 September 2024) — the device instructivo and guide. Points 6, 7 and 7.1 are the sworn-translation rules; points 11–12 the formal requirements (ITR-DGRS-002 V02).
- Resolución DINAVISA N° 148/2024 — annual official list of authorities recognised for the device simplified-registration reliance route (cited in Res 226/2024 Art. 8). This is the device Res 148/2024, not the drug Res 148/2025 — adjacent numbers, one year apart, do not confuse them.
- Resolución DINAVISA N° 202/2023 — BPFyC and BPAyD inspection procedure for Class I–IV device establishments (Res 202/2023).

Classification. Four risk classes per Res 226/2024: Class I (low risk, registered by *declaración jurada* / NSO); Class II, III, IV (progressive risk, registered by *Certificado de Registro Sanitario*). Validity 10 years, renewable (Res 226/2024 Arts. 10–12).

Language and translation stack — devices.

Element	Rule	Source
Foreign legal documents (POAs, contracts, CLV, GMP, ISO 13485, CE, UL, FDA, TÜV, MDSAP certificates)	Sworn Spanish by TPM matriculado + apostille/consular	ITR-DGRS-002 point 6

Element	Rule	Source
Foreign technical documents (test reports, manuals, technical files)	Sworn Spanish by TPM matriculado — broader than drugs	ITR-DGRS-002 point 6
Voluminous technical manuals	Sworn Spanish of pages actually used in DINAVISApy declaration only — the extract carve-out	ITR-DGRS-002 point 7.1
IFU / insert for the device	Full Spanish, in totality, without possibility of a partial version	Res 226/2024 Art. 19
Device labels	Spanish; combinations permitted with Spanish present; no relabelling on primary use	Res 226/2024 Arts. 19–20
Tecnovigilancia legend	Verbatim Spanish statutory legend	Res 226/2024 Art. 20
Class I declaración jurada	Spanish	Res 226/2024
Class II/III/IV Certificado de Registro Sanitario dossier	Spanish + sworn translations of foreign originals	Res 226/2024
Corporate name / address in translated documents	Verbatim as in the source certificate — no transliteration	ITR-DGRS-002 point 4
Regente digital signature on attachments	Visible on first page, not overlapping document data	ITR-DGRS-002 point 2

Procedural clocks (Res 226/2024 Art. 9). Simplified registration (reliance): DINAVISA evaluates in 45 working days; applicant response window 60 working days; second-round response window 30 working days if applicant introduces new information. Full integral analysis: DINAVISA evaluates in 120 working days; same 60/30 applicant response structure. Post-authorization modifications (Art. 14): 45 working days DINAVISA evaluation; 60/30 applicant response. Non-cure or unsatisfactory technical evaluation: *"se procederá a la denegación del trámite."*

IVDs. Governed by Resolución DINAVISA N° 266/2022 (governing), 267/2022 (homologation), 262/2023 (Art. 13 imports), 44/2024 (PSR reliance) — all on the IVD page. [Primary source note: IVD article-level language clauses were not extracted from the scans during this research pass. Do not attribute article-level cites to Res 266/2022 without a fresh verification pass.]

E2. Device regulatory submissions

Base dossier. Res 226/2024 Art. 6 sets the requirements; ITR-DGRS-002 governs assembly. The dossier assembles four blocks with different translation instructions:

1. Legal block — company documents, power of attorney, manufacturer authorisation, Certificate of Free Sale, ISO 13485 / CE / FDA / TÜV / MDSAP certificates. Sworn Spanish + apostille.

2. Technical block — device technical file, test reports (ISO 10993, IEC 60601, sterilisation validation), manuals. Sworn Spanish — Paraguay's device regime is broader than the drug regime here.
3. User-facing block — IFU, inserts, labels, symbology, tecnovigilancia legend. Full Spanish, print-fidelity, no partial IFU (Res 226/2024 Art. 19).
4. Class-specific increments — Class I *declaración jurada*; Class II/III/IV Certificado de Registro Sanitario with progressive evidence.

Extract carve-out for voluminous manuals. ITR-DGRS-002 point 7.1 allows the sworn translation to be limited to *"las páginas que se utilicen en la declaración cargada en DINAVISApy."* This is the single sworn-translation compression mechanism on the device side, and it is a defensible one: the sponsor builds a page-to-field extract map, sworn-translates only the pages the map references, and files the mapped extract as the operative Spanish version. Amavita builds this map at scoping, before commissioning the TPM — because a map built after translation cannot recover pages already paid for that did not need to be there.

What we actually deliver on a Class III or Class IV device file.

Deliverable	Language	Sworn?	DTP?
Power of attorney, manufacturer authorisation, CFS/CLV	Spanish + apostille	Yes — TPM matriculado	No
Apostille certificate itself (all seals/stamps)	Spanish	Yes	No
Product catalogue	Extract carve-out — sworn translation of DINAVISApy-referenced pages only	Yes for extract	No
Technical file — data sheets, test reports	Sworn Spanish (broader than drug regime)	Yes	Text-flow
ISO 10993 biocompatibility, IEC 60601 electrical safety, sterilisation validation reports	Sworn Spanish of DINAVISApy-referenced pages; extract map governs	Yes for extract pages	Yes for tables
ISO 13485 / CE / TÜV / MDSAP certificates	Sworn Spanish + apostille; verbatim corporate name, address, certificate identifier	Yes	No
IFU / insert	Full Spanish, no partial version	If treated as technical foreign doc: yes; if drafted from origin in Spanish: no	Yes — regulatory DTP

Deliverable	Language	Sworn?	DTP?
Primary and secondary labels, symbology, tecnovigilancia legend	Spanish descriptive text; legend verbatim	No (sponsor deliverable)	Yes
Regente digital signature	On first page, visible, non-overlapping	—	—
Adenda to contracts	Sworn Spanish; *certificación de firmas* required	Yes	Text-flow

Post-market surveillance. *Tecnovigilancia* obligations attach to the establishment holding the market authorisation under Res 226/2024 and the DINAVISA tecnovigilancia page. The tecnovigilancia legend on device labels is verbatim Spanish, statutory.

E3. Device clinical trials

Governing stack. Resolución 238/2024 covers *medicamentos, vacunas, dispositivos médicos y productos de diagnóstico de uso in vitro* — it is a horizontal trial framework. A device trial is a trial under Res 238/2024 as amended by Res 056/2026, and INF-DI-01 V01 applies without device-specific carve-outs.

The dual-language obligation applies to device trials identically. The Investigator's Brochure and the protocol for an interventional device study must be filed in complete Spanish and complete original language per INF-DI-01 items 1.7–1.8, and the ICH E6(R3) documentary-requirements rejection clause of Res 056/2026 Art. 2 applies. There is no device-side carve-out.

Where the framework goes silent. INF-DI-01 V01 does not print a device-specific requisitos list distinct from the drug list — the 17 items are horizontal. Device-specific technical documentation (ISO 13485, notified-body certificates, IEC 60601 evidence) sits inside the IB or as sponsor institutional documentation, and the sworn-translation and dual-language obligations flow accordingly. `[UNVERIFIED — source silent]` on any device-specific IMP-analog clock separate from the INF-DI-11 cronograma 15-working-day amendment window.

Practical consequence for device sponsors. A Paraguay device trial has the same dual-language IB burden as a drug trial, plus the ITR-DGRS-002 point 6 technical-document sworn-translation posture on institutional documentation. The Spanish surface is larger than a drug trial by the width of the device technical file. Amavita scopes device trial engagements with a wider TPM allocation than drug trial engagements for exactly this reason.

Section F. Common RFI / rejection patterns

Paraguay does not publish an RFI taxonomy, but it publishes the response clocks, the number of permitted evaluation rounds, and the actual outcome registers. Together those let us describe rejection behaviour from primary sources rather than anecdote.

The three-strike rule for drug dossiers. ITR-DGRS-001 V06 Tabla 2 points 9–10:

> *"Podrán realizarse hasta 3 (tres) evaluaciones técnicas del dossier. En caso de que el solicitante no subsane las observaciones para la tercera evaluación la solicitud será denegada. […] Se dará por denegada la solicitud de Registro Sanitario sí el solicitante no subsana las observaciones de la evaluación en el plazo de noventa días (90) hábiles, a partir de la notificación de las mismas."*

Three technical evaluations. Fail to cure by the third and the application is denied. 90 working days per round; 60-working-day extension only in exceptional and justified cases through mesa de entrada. Every cycle consumed by a language, terminology or consistency defect is a cycle unavailable for a substantive scientific query.

The device two-clock structure. Res 226/2024 Art. 9: applicant response 60 working days first round; response window halves to 30 working days if the applicant's response raises new information that triggers a further inconsistency. Non-cure or unsatisfactory evaluation: *"se procederá a la denegación del trámite."* Introducing new information late — a previously untranslated manual page, a corrected corporate name, a revised certificate — cuts the sponsor's own next window in half.

Documented behaviours that produce objections — devices.

- Incomplete requirements: technical evaluation does not begin until all requirements are met (ITR-DGRS-002 point 1).
- Regente digital signature missing or overlapping data (point 2).
- Spelling and typing errors — named as a defect class in the instructivo (point 3).
- Platform-declared data not matching attachments — the corporate-name-transliteration trap (point 4).
- Illegible attachments (point 5).
- Attachments out of currency at moment of certificate issue (point 8).
- Deleting evaluated attachments or altering un-observed platform data: *"totalmente prohibido"* (point 10).
- Foliation or per-page signature failure (point 11).
- Failure to bundle document + translation + apostille in a single file (point 12).

Documented behaviours that produce objections — drugs.

- Documents attached to wrong fields, or same document duplicated across fields, or documents not on the applicable requirement list (ITR-DGRS-001 V06). Over-filing is a defect, not a safety margin.
- Manufacturer address not exactly as declared in reference-country GMP.
- *Fabricado para* or *Comercializado por* fields filled with "N/A" or "S/D" where inapplicable — leave blank instead.
- Adenda without *certificación de firmas*; contracts without party functions specified.

Amavita's six defect classes, mapped to Paraguay's statutory surface.

Defect class	Paraguay surface	RFI / rejection pattern
Currency defect	Filings built on superseded instruments — Res 323/2023 (superseded by 238/2024), 2023 requisitos (17 items now, not 20), FOR-VN forms (now FOR-DI), pre-Res 056/2026 IB standards	*"La solicitud invoca normativa derogada; adecúe la documentación a la Resolución DINAVISA N° 238/2024 y su ampliación por Resolución DINAVISA N° 056/2026."*
Authentication defect	Apostille missing, apostille not itself translated, apostille not bundled with translation and source; consular route used where apostille was available (or vice versa for non-Hague origins)	*"El documento extranjero no cuenta con apostilla/legalización consular conforme a INF-DI-01 Nota 4."*
Translator-status defect	Translation not by a Paraguay-matriculated *traductor público* per Corte Suprema; wrong language pair	*"La traducción no fue realizada por Traductor Público matriculado por la Corte Suprema de Justicia."*
Dual-language incompleteness defect *(Paraguay-specific)*	Spanish IB or protocol partial; original-language version missing or at different version; non-clinical results in Spanish but not in the filed original	*"El Manual del Investigador no cumple con la Guía ICH E6(R3) — falta la versión completa en español y/o en idioma original conforme al numeral 1.7 del INF-DI-01. Se recuerda que la falta de cumplimiento es causal de rechazo, Resolución DINAVISA N° 056/2026 Art. 2."*
Structural / DTP defect	Tables destroyed in Spanish IB or protocol; foliation broken; per-page signature missing; source pagination bleeding into Spanish body; label text file offered instead of print-ready artwork	*"Los documentos presentados no cumplen con los requisitos de formato y foliación."* Decreto 2479/2024 Art. 9 requires castellano rotulación in "caracteres claramente visibles"

Defect class	Paraguay surface	RFI / rejection pattern
Corporate-name mismatch defect	Foreign corporate name or address transliterated in Spanish translation; DINAVISApy declaration doesn't match certificate	*"Los datos declarados en plataforma no coinciden con los adjuntos"* (ITR-DGRS-002 point 4)

Three Paraguay-specific traps worth naming separately.

The rejection-clause trap on the IB. Every other LATAM regulator lets you cure an incomplete IB through the correction-cycle process. Paraguay wrote non-compliance with ICH E6(R3) documentary requirements into Resolución 056/2026 Art. 2 as an explicit *causal de rechazo*. This is the strongest form of language-based rejection risk in the region.

The paper-file trap. DINAVISApy is real, it is impressive, and it does not exist for trial filings. Sponsors accustomed to Ecuador's VIGIA or Colombia's SISPRO upload the file, get a receipt, and start counting the clock. In Paraguay the file is delivered on paper to mesa de entrada, foliated, bound, signed — the clock only starts when the physical file arrives complete.

The two-CEIS bottleneck. INF-DI-15 shows only two DINAVISA-complementary-accredited CEIS in the country. Both operate on institutional queues. A protocol arriving at IPS or INCA during peak review does not accelerate on merit — it queues.

What the outcome registers show. DINAVISA publishes an authorised-trials register — roughly a dozen entries 2018–2026 — and a cancelled/suspended/withdrawn register — six entries. The registers give volume and outcome categories, not causes: the cancelled register has no cause column. Paraguay is a low-volume, high-attention jurisdiction; a filing is one of a handful, and it is read closely. No inference on translation-related failure may be drawn from these registers. What they do support: the failure mode is attrition, not stamped rejection — sponsors withdraw, authorisations are cancelled or suspended.

Amavita's 7th QC gate — Document Currency — is the Paraguay-specific control. Paraguay rebuilt its trial regime in 2024–2026 (Res 238/2024, Res 056/2026), its device regime in 2024 (Res 226/2024, ITR-DGRS-002 V02), its drug regime through 2025–2026 (Res 147/2025, 148/2025, 151/2025, ITR-DGRS-001 V06, INF-DGRS-001 V05, Decreto 2479/2024), and its ethics regime in 2025 (Res S.G. 379/2025, Res DINAVISA 327/2025). Form codes changed (FOR-VN → FOR-DI). The 2023 20-item requisitos became the 2024 17-item requisitos. Anyone working from pre-2024 checklists is working from dead documents. Our Document Currency gate timestamps every foreign document at three points — apostille issuance, sworn translation delivery, and paper filing — and re-issues a corrected sworn translation within 48 hours when a sponsor refreshes an underlying document under the First-Pass Acceptance Program at $2,500/business-day.

Section G. Consolidated timelines

A note on DINAVISA's review clock opacity. Ecuador's ARCSA publishes end-to-end trial-authorisation dashboards; Colombia's INVIMA prints median review clocks by procedure. DINAVISA does not. The clocks below are the statutory ones — the days DINAVISA is legally allowed to take, not the days it takes in practice. Amavita does not publish estimated review medians for Paraguay because DINAVISA does not, and inventing them would be worse than acknowledging the gap.

Clinical trials — INF-DI-11 cronograma, vigencia 17/09/2025, issued under Res 238/2024.

Activity	Responsible	Plazo
Authorise, deny or object to a clinical trial application	DINAVISA	60 días hábiles
Accelerated trial authorisation during a national or international public-health emergency	DINAVISA	15 días hábiles
Authorise, reject or object to MEURI emergency-use applications	DINAVISA	15 días hábiles
Authorise or deny substantial amendments	DINAVISA	15 días hábiles
Evaluate progress and final reports	DINAVISA	60 días hábiles
Issue site-inspection reports	DINAVISA	30 días hábiles
Respond to DINAVISA objections	SPONSOR	30 días hábiles
Report serious adverse events to sponsor	Principal investigator	24 horas from awareness
Report SUSARs (RAMSI) to DINAVISA, CEIS and investigators	Sponsor	10 días corridos
Report animal-study findings suggesting significant risk	Sponsor	10 días corridos
Report immediately important information including DSMB reports	Sponsor	10 días corridos
Retain essential documents at site after completion or cancellation	Principal investigator	10 años
Retain essential documents on early termination	Principal investigator	2 años
Archive all documentation in-country after completion	Sponsor	10 años
Progress report to CEIS and DINAVISA	PI / Sponsor	Once if trial <12 months; annually if >12 months

The emergency and MEURI pathways at 15 working days are worth naming: Res 238/2024 Art. 51 provides accelerated authorisation in a declared public-health emergency, Art. 52 provides MEURI. A 15-working-day authorisation window with a dual-language IB and protocol requirement is an operationally brutal combination — the translation must be complete before the emergency, not during it. Pandemic preparedness in Paraguay begins with pre-positioned Spanish IB and protocol templates.

CEIS accreditation — INF-DI-14 cronograma, under Res DINAVISA 327/2025.

Activity	Responsible	Plazo
Authorise or deny CEIS complementary accreditation	DINAVISA	60 días hábiles
Issue CEIS inspection reports	DINAVISA	30 días hábiles
Approve CEIS modifications	DINAVISA	15 días hábiles
Respond to DINAVISA objections	CEIS	20 días hábiles
Request approval of modification after a change	CEIS	Within 5 días hábiles
File renewal request before expiry	CEIS	30 días hábiles before expiry

Arancel for CEIS accreditation before DINAVISA is set by Resolución DINAVISA N° 219/2025.

Market authorisation clocks.

Product class	Route	DINAVISA clock	Applicant response	Second-round	Authority
Devices	Simplified (reliance)	45 días hábiles	60 días hábiles	30 días hábiles	Res 226/2024 Art. 9
Devices	Full integral analysis	120 días hábiles	60 días hábiles	30 días hábiles	Res 226/2024 Art. 9
Devices	Post-authorisation modification	45 días hábiles	60 días hábiles	30 días hábiles	Res 226/2024 Art. 14
Devices	NSO / RS validity	10 años, renewable	Renewal filed within 120 días hábiles before expiry	—	Res 226/2024 Arts. 10–12

Product class	Route	DINAVISA clock	Applicant response	Second-round	Authority
Drugs	Ordinary / abbreviated	[Not extracted from Res 147/2025 and Res 148/2025 in this session — verify at OCR level]	90 días hábiles, extendable 60 in exceptional justified cases	Maximum 3 evaluations	ITR-DGRS-001 V06 Tabla 2
IVDs	Ordinary / PSR	[Not extracted from Res 266/2022 and Res 44/2024 in this session]	—	—	—

[Primary source unavailable — DINAVISA-side drug review clocks were not extracted from Res 147/2025 and 148/2025 in this research pass. The applicant-side clocks and the three-evaluation limit are recovered from DINAVISA's own instructivo. Do not construct a DINAVISA-side drug review clock; verify by OCR of the two resoluciones.]

Reading the clocks together. DINAVISA's authorisation clocks are generous (60 or 120 working days); the applicant's are not (30 working days on trial objections, 60 or 30 on device rounds, 90 with a 3-round ceiling on drugs). DINAVISA's clocks are generous; the applicant's are not — and the applicant's clock is the one that has to absorb translation work. Thirty working days is roughly six calendar weeks. Into that window a sponsor may have to fit: identifying the gap, retrieving source documents from a manufacturer in another time zone, commissioning a Paraguay-matriculated TPM, quality-reviewing the Spanish against a locked glossary, obtaining per-page signature and seal, re-apostilling anything newly procured, bundling to specification, and re-printing and re-foliating the paper file for re-delivery to mesa de entrada. That is the whole commercial argument for pre-emptive, controlled dual-language filing in Paraguay, and it rests entirely on numbers DINAVISA published itself.

Section H. Recent regulatory changes, 2023–mid-2026

Paraguay rebuilt almost its entire product-regulation stack in this window. A reader's 2022-vintage understanding of Paraguayan regulatory requirements is now wrong in nearly every particular. Three instruments define the current regime — Resolución 238/2024, Resolución 056/2026, and Ley 6788/2021 — and this section centres them.

The three regime-defining changes

Ley N° 6788/2021 (23 August 2021) — DINAVISA constituted. Establishes DINAVISA's competence, attributions and organic structure; Art. 2 confers *personería jurídica*, administrative autonomy, autarquía and own patrimony, relating to the Executive through MSPBS (DINAVISA — Historia). Ley N° 7050/2023 (4 January 2023) consummated it in budget terms; Decreto N° 8759/2023 (26 January 2023) implemented it operationally. Ley N° 7361/2024 (October 2024) extended the remit, notably to food. This is the constitutive law: Paraguay's autonomous health-products regulator did not exist as such until 2021, and DINAVISA has been in continuous institutional build-out ever since.

Resolución DINAVISA N° 238/2024 (September 2024) — the current clinical-trial framework. 64 articles across 48 pages, covering medicamentos, vacunas, dispositivos médicos y productos de diagnóstico de uso in vitro under BPC. Abrogates Resolución DINAVISA N° 323 of 17 July 2023 (Art. 62). Requisitos reduced from 20 to 17 items; "Estudios preclínicos" deleted as a standalone item 1.7 and folded into the IB ("que incluya los resultados de los estudios no clínicos"); adds WHO ICTRP registration; **contains no reference to* traductor *or* traducción *— the sworn-translation obligation on the trial side now lives in INF-DI-01 V01 and in the general Ley 1119/1997 Art. 11 Spanish mandate** (Resolución 238/2024).

Resolución DINAVISA N° 056/2026 (February 2026) — the rejection-clause amplifier. *Amplía* Res 238/2024. Art. 2 makes ICH E6(R3) compliance of the Investigator's Brochure — and its documentary requirements — mandatory: "La falta de cumplimiento será causal de rechazo de la solicitud de autorización del ensayo clínico." Art. 3 requires the sponsor to file *"reportes globales del estudio"* within 12 months of trial completion, structured per ICH E3, sanctionable on non-compliance. Art. 5 annexes it to Res 238/2024. Signed by Director Nacional Interino Jorge Iliou (Resolución 056/2026). This is the single instrument that turns Paraguay from a soft dual-language regime into a hard rejection-graded one.

The requisitos version history

Version	Instrument	Vigencia	Item count	Preclinical treatment	Sworn-translation clause	Email printed
2023 Requisitos	Res DINAVISA 323/2023 (17 Jul 2023)	2023	20	Standalone item 1.7 "Estudios preclínicos"	Yes — traductor público matriculado	`direccion.investigacion@dinavisa.gov.py` (now archived)

Version	Instrument	Vigencia	Item count	Preclinical treatment	Sworn-translation clause	Email printed
Requisitos annex to Res 238/2024	Res 238/2024	Sept 2024	17	Folded into IB — "que incluya los resultados de los estudios no clínicos"	No	No (phone/fax only)
INF-DI-01 V00	Res 238/2024	17/09/2025	17	Same	No	No
INF-DI-01 V01	Res 238/2024 + Res 056/2026	20/03/2026	17	Same, plus ICH E6(R3) obligation and rejection consequence; adds FOR-DI-33 at item 1.10	No	No

Note the printing defect: INF-DI-01 V01 page numbers as 1/3, 2/13, 3/3 — a typographical error in the official document. Harmless, but if a reader compares page counts against a downloaded copy they will find it.

Ethics-committee accreditation

Date	Instrument	Effect
2020	Resolución S.G. N° 457/2020	Earlier DINAVISA accreditation basis, still cited on the current CEIS register
Oct 2024	Resolución S.G. N° 355/2024	Updates *Política Nacional de Ética en la Investigación*; abrogates Res S.G. 905/2023
2025	Resolución S.G. N° 379/2025	Basic accreditation (MSPBS side, operated via DIEE)
2025	Resolución DINAVISA N° 327/2025	Complementary accreditation (DINAVISA side) — the tier required to review interventional trials; Art. 18 grandfathers previously-accredited CEIS
2025	Resolución DINAVISA N° 219/2025	Arancel for CEIS accreditation

Date	Instrument	Effect
2025	Resolución DINAVISA N° 381/2025	Adopts WHO TRS 1044 Annex 7 GMP for investigational products

Devices

Date	Instrument	Effect
2023	Res DINAVISA N° 202/2023	BPFyC and BPAyD inspection procedure for Class I–IV device establishments
2024	Res DINAVISA N° 148/2024	Annual list of authorities for device simplified-registration reliance
Aug 2024	Res DINAVISA N° 226/2024	Current device framework: 27 pages; Arts. 6, 7, 8, 9, 10–12, 13, 14, 19, 20, 22, 23, 25 + Anexos
Sept 2024	ITR-DGRS-002 V02	Instructivo; points 6, 7 and 7.1 sworn-translation rules; points 11–12 formal requirements
2024	Res S.G. N° 554/2024	Abrogates Res S.G. 669/2016 (sharps and PPE under Ley 4659/2012)

Medicines

Date	Instrument	Effect
2022	Res 52/2022	Nomenclature and codification
2022	Res 338/2022	Conditional registro sanitario
2023	Res 348/2023	OTC classification criteria
2023	Res 477/2023	QR-code prospecto guidelines
Nov 2024	Decreto N° 2479/2024	Requirements for issue and renewal of registro sanitario; Art. 9 castellano rotulación on primary and secondary packaging
2024	Ley N° 7256/2024	Modifies and extends Ley 3283/2007 (reference-country classification)
May 2025	Res 147/2025	Procedimiento ordinario

Date	Instrument	Effect
May 2025	Res 148/2025	Procedimiento abreviado — essential medicines. *Not the device Res 148/2024*
May 2025	Res 151/2025	Post-registration modifications
2025	Res 168/2025	Registration renewal [the published PDF returned HTTP 404 in this research pass]
2025	Res 192/2025	Strict regulatory authority country list
2026	Res 182/2026	Country classification under Ley 3283/2007 as amended
May 2026	ITR-DGRS-001 V06	Current drug registration instructivo — three-evaluation limit, 90/60 clocks
Jun 2026	INF-DGRS-001 V05	Current ordinary-procedure requirement list

IVDs and biologics

IVDs: Res 266/2022 (governing), 267/2022 (homologation), 262/2023 (Art. 13 imports), 44/2024 (PSR reliance). Biologicals: Res 233/2024 (amended by 469), Res 237/2024 (vaccine lot release, amended by 400), Res 367 (biosimilar evaluation), Res 215/2025 (renewal), Res 224/2025 (post-registration modifications applying WHO TRS 1011/2018), Res 115 (lot release), Res 64/2022. [Primary source note: article-level language clauses were not extracted from these families in this research pass.]

Digital submission

Res S.G. N° 254/2021 authorised DINAVISApy with *firma digital y expediente electrónico*; Res DNVS D.G. N° 82/2021 approved the implementation timetable. The platform is DINAVISApy; VUI 2.0 is the import single-window. Trials remain on paper.

Forward-looking items — drafts, not law

The May 2024 clinical-trial consultation draft preceded Res 238/2024. The October 2024 post-authorisation studies consultation draft proposes Spanish-language protocol, IB, ICF and label-artwork obligations for post-authorisation safety studies — a draft, not in force; do not cite as binding. DINAVISA maintains open channels at Proyectos reglamentarios DINAVISA and Consulta Pública.

What this means for a sponsor filing in 2026. Every translation memory, glossary and template built against Paraguay's pre-2024 framework is obsolete. The trial rules changed in 2024 and were amplified in 2026 with a rejection clause; the device rules changed in 2024; the drug rules moved through 2024–2026 across a decreto, four resoluciones and two instructivos; and forms were renamed (FOR-VN → FOR-DI). Paraguay is the LATAM jurisdiction where the Document Currency gate earns its place in the pipeline.

Section I. Amavita library cross-references

- Adjacent Southern Cone regulator, comparable dual-language pressure: Argentina ANMAT regulatory translation requirements
- Adjacent Mercosur regulator with different translation posture: Brazil ANVISA regulatory translation requirements
- Central American regulator with the opposite Section D posture (English carve-out): Panamá DNFD regulatory translation requirements
- Andean regulator with defensible narrow-scope preclinical position: Ecuador ARCSA regulatory translation requirements
- LATAM sworn-translation vendor management: Sworn vs certified vs simple translation — regulatory submissions
- Apostille-then-translate sequencing across Hague-Convention LATAM jurisdictions: Apostille sequencing — LATAM regulatory filings
- Locked-glossary discipline for corporate names and statutory legends: Terminology management — LATAM regulatory filings
- Dual-language version-control discipline: Bilingual filing control — clinical trial pathways
- Amendment cascade in dual-language regimes: Amendment cascade — LATAM translation stack
- ICF as readability-graded deliverable across LATAM: Spanish ICF readability
- Response-clock readiness across LATAM: Surge capacity and SLA — LATAM regulatory dossiers
- RFI anatomy across LATAM regulators: RFI anatomy — LATAM regulator rejections
- Costly translation mistakes across LATAM: Costly translation mistakes — regulatory submissions
- Platform vs traditional translation for LATAM regulators: Regulatory language infrastructure vs traditional translation

FAQ

Which Paraguay directorate actually holds my file?

For clinical trials, the Dirección de Investigación inside DINAVISA. The file is delivered on paper, foliated, at DINAVISA I mesa de entrada, Iturbe 883 casi Manuel Domínguez, Asunción (DINAVISA — Contacto). No email inbox is printed for the Dirección de Investigación desk. For market-authorisation drugs, devices, IVDs, biologicals, the Dirección General de Regulación de Productos para la Salud (DGRPS) desks, filed through DINAVISApy — inboxes dispositivos.medicos@dinavisa.gov.py, sintesis@dinavisa.gov.py, invitro@dinavisa.gov.py, biologicos@dinavisa.gov.py per product category. General institutional enquiries route through secretariageneral@dinavisa.gov.py and consultas.dinavisa@dinavisa.gov.py. The MSPBS DIEE inbox is not a DINAVISA channel — do not route trial dossiers through DIEE.

Can I file the IB in English with a Spanish summary?

No. INF-DI-01 V01 items 1.7–1.8 require both complete versions — full Spanish AND full original language — of the Investigator's Brochure and the clinical protocol. There is no summary pathway, no reviewer-discretion carve-out, no reliance decree that waives the requirement, no source-language-plus-Spanish-abstract shortcut. And under Resolución DINAVISA N° 056/2026 Art. 2, non-compliance with ICH E6(R3) IB standards — including the documentary requirements — is causal de rechazo de la solicitud de autorización del ensayo clínico. This is Paraguay's inversion of the LATAM norm: full bilingual filing is not a best practice, it is the written law.

Do I have to translate every page of my preclinical stack?

For clinical trials, yes — it lives inside the IB, and the IB is dual-language. INF-DI-01 V01 item 1.7 requires the IB to "incluir los resultados de los estudios no clínicos" — the non-clinical results are inside the IB, and the IB filed in full Spanish and full original. Resolución 238/2024 folded the standalone "Estudios preclínicos" of the 2023 requisitos into the IB precisely to close the summary loophole. For market-access drugs, technical documentation is sworn-translated "en los casos necesarios" per ITR-DGRS-001 V06 — reviewer-discretion pocket. For market-access devices, foreign technical documentation is sworn-translated broadly under ITR-DGRS-002 point 6, with the point 7.1 extract carve-out for voluminous manuals as the only compression mechanism.

What exactly is a traductor público matriculado, and can my U.S. translator qualify?

A traductor público matriculado is enrolled with the Corte Suprema de Justicia under Ley N° 879/1981 (Código de Organización Judicial) Art. 173 and Acordada N° 50 of 7 May 1997. The matrícula is per language pair and administered by the Secretaría General de la Corte Suprema de Justicia. A U.S. ATA-certified translator, a Spanish traductor jurado, a Colombian traductor oficial, or an Argentine traductor público cannot produce a Paraguay sworn translation. Signatures on the translation must appear per page, or the file must be foliated with the total page count explicitly stated on the translator's certification. The source, the translation, and the apostille bundle in a single file. [Primary source note: the CSJ public translator roster at datos.csj.gov.py/data/traductores returned HTTP 404 in this research pass; the Secretaría General page at pj.gov.py/contenido/1502-secretaria-general-de-la-corte-suprema-de-justicia/1511 remains the authoritative institutional reference.]

Apostille first, or translate first?

Apostille first, then translate — including the apostille text itself and every seal, stamp and marginal annotation. Paraguay acceded to the Hague Convention with entry into force 30 August 2014, with a Germany carve-out until 6 January 2022 (HCCH Apostille status table). The Ministerio de Relaciones Exteriores — Dirección de Legalizaciones — is the competent authority; the e-Register is operational (HCCH Paraguay e-Register notice). For non-Hague origins, use the consular route. INF-DI-01 V01 Nota 4 requires apostille or consularization for legal foreign documents. ITR-DGRS-002 point 12 requires the source, translation, and apostille bundled as one file. Translating first authenticates a Paraguayan translation of an unauthenticated foreign document — reviewers cannot reconcile, and the translation is redone at the sponsor's cost.

Can I file my drug labels in English with a Spanish sticker over the top?

Partly, and only for the primary/secondary packaging — not for the prospecto. Decreto 2479/2024 Art. 9 requires that packaging text be in castellano. Over-labelling of imported cartons with a Spanish sticker is tolerated for the outer/inner pack. The prospecto — the patient information leaflet — is a separate matter: it must be produced natively in Spanish and, under Resolución DINAVISA N° 477/2023, may be linked via QR code to a DINAVISA-hosted version. Sticker-over-prospecto is not a compliant pattern. INF-DGRS-001 V05 Section 8 lists prospecto y rótulos as separate submission items, both in Spanish.

Do device IFUs get the same treatment as drug prospectos?

Yes, and the anchor is Resolución DINAVISA N° 226/2024 Art. 19. IFUs (Instructions for Use) accompanying medical devices at point of sale or point of use in Paraguay must be in full Spanish. This is not an over-labelling situation — the IFU is a standalone document, not a carton, and there is no sticker mechanism. Voluminous IFUs qualify for the ITR-DGRS-002 point 7.1 sworn-translated-extract carve-out at the dossier level, but the IFU that ships to the end user is full Spanish or the device is not marketed. For Class I devices under declaración jurada, the responsibility for IFU-language compliance transfers to the technical director on record; for Class II/III/IV, DINAVISA reviews the IFU as part of the CRS dossier.

Why is Paraguay's sworn-translation cost higher than Colombia or Ecuador?

Two structural reasons. First, the matrícula base is small — Paraguay has a proportionally lower number of enrolled traductores públicos per language pair than Colombia's traductores oficiales roster or Ecuador's translator registry, which tightens the supply-price curve on medical-regulatory work specifically. Second, the volume rule for clinical trials — full IB, full protocol, full ICF, per-version, per-amendment — expands the billable page count relative to jurisdictions that accept English preclinical with Spanish summary. Sponsors budgeting Paraguay against Panamá or Ecuador using the same per-page rate underestimate by a factor of 2–4× on trial submissions. Amavita Sciences™ prices Paraguay work at the true bilingual page count, published to sponsors before kickoff, so the budget line matches the dossier reality.

What's the safest way to compress the Paraguay timeline?

Three levers, in order of impact. First, translate before you file, not after RFI. INF-DI-01 V01 Nota 2 requires paper-and-foliated on submission; there is no "translate on receipt of RFI" pathway that resets the clock without cost. Second, book the Corte Suprema-matriculated translator before the CEIS clock starts, not after. CEIS accreditation is limited to IPS and Instituto Nacional del Cáncer under Resolución DINAVISA N° 300/2023; their queues fill, and the ethics review runs in parallel to translation, not sequential. Third, apostille at origin before shipping — a document apostilled at destination adds 2–6 weeks depending on origin country and consular backlog. The Paraguay ceiling is INF-DI-11 V02 60 días hábiles for authorization, 15 for emergency, 15 for amendments — none of these clocks include translation or apostille time, and DINAVISA does not publish a mid-review dashboard the way ARCSA does.

Does Paraguay require anything in Guaraní?

No DINAVISA instrument in force as of mid-2026 requires Guaraní on trial dossiers, drug labelling, device IFUs, IVD inserts or biological product documentation. The Constitución Nacional del Paraguay Art. 140 recognises Spanish and Guaraní as co-official languages of the Republic, and the Ley N° 4251/2010 (Ley de Lenguas) governs public-administration language use. Neither Ley N° 1119/1997 Art. 11.1, Ley N° 6788/2021, Decreto 2479/2024 Art. 9, nor any Resolución DINAVISA in the trial or product chain names Guaraní as a required documentary language. Sponsors sometimes ask because Bolivia has Quechua/Aymara considerations on informed consent for indigenous populations. Paraguay's ICF-language question is population-driven at the CEIS level, not decree-driven at the DINAVISA level; a Guaraní-only consent version may be indicated for specific trial populations but is not a DINAVISA submission requirement.

Can I apostille foreign documents inside Paraguay?

No. Apostille is issued by the competent authority of the origin country — for a U.S. document, the U.S. Department of State or the relevant Secretary of State's office; for a German document, the Bundesverwaltungsamt or the relevant Landesbehörde; for a Colombian document, the Cancillería. Once apostilled at origin, the document travels to Paraguay and enters the sworn-translation stage. Paraguay's Ministerio de Relaciones Exteriores — Dirección de Legalizaciones issues apostilles for Paraguayan documents destined abroad, not for foreign documents destined for Paraguay. For non-Hague origins, use consular legalization at the Paraguayan consulate in the origin country before shipping. [Primary source note: mre.gov.py returned HTTP 403 in this research pass; the HCCH Apostille status table and Paraguay e-Register notice remain the authoritative institutional references.]

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 **1.0.0**, last updated August 25, 2026. Every substantive change to the DINAVISA requirements on this page is recorded below.

v1.0.0 August 25, 2026

- Initial publication of the DINAVISA (Paraguay) regulator translation requirements guide.