LATAM REGULATORY GUIDES · EL SALVADOR

SRS Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in El Salvador

The DNM to SRS succession, the RTCA 11.03.59:18 Mutual Recognition launchpad into five neighbouring markets, and the narrowest castellano surface in LATAM.

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

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SRS succession — Aug 2024

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The direct answer

El Salvador is the only regulator in LATAM's core seven where the authority itself was replaced during the current filing cycle — the *Superintendencia de Regulación Sanitaria* (SRS) legally succeeded the *Dirección Nacional de Medicamentos* (DNM) on 7 August 2024 under Legislative Decree No. 891 and its June 2024 reforms, absorbing DNM's competencies plus registration

functions previously exercised by the Ministerio de Salud, the Ministerio de Agricultura y Ganadería, and the *Consejo Superior de Salud Pública* (CSSP) (SRS Ley; Asamblea Legislativa). Every technical regulation — the *Ley de Medicamentos* (Decreto Legislativo No. 1008), the RTCA harmonized instruments, and the RTS 11.03.02:21 for medical devices — remains in force, but the authority receiving the dossier, signing resolutions, and running inspections is now the SRS. Existing DNM sanitary registrations remain valid; new filings, renewals, and clinical-trial submissions are decided by the SRS (LatinAlliance).

The second structural fact: El Salvador operates inside the Central American harmonized framework (RTCA), so a compliant El Salvador drug dossier is largely reusable in Guatemala, Honduras, Nicaragua, Costa Rica, and Panama through Mutual Recognition under RTCA 11.03.59:18 Anexo 2 (SRS RTCA). Its official-language footprint is also the narrowest in the region: castellano is mandatory only for device labelling, IFU/manuals of used or refurbished biomedical equipment, and clinical-trial protocols/ICFs; the ethics-committee manual (CNEIS) permits the *original investigator's brochure in its source language with a Spanish summary*, and the pharmaceutical registration guide reserves *traducción oficial* (sworn translation) for legal-administrative documents — Carta de Representación, apostilles, powers of attorney, foreign certificates of pharmaceutical product — not for technical evidence (Manual CNEIS; RTS 11.03.02:21).

For a Miami-based sponsor, El Salvador is best understood as a transition-risk jurisdiction stacked on top of a regional-recognition jurisdiction. Amavita's 7th QC gate — Document Currency carries dual weight here: the underlying foreign document must be current *and* it must be prepared for either the DNM legacy expedient or the SRS successor expedient — and increasingly, for onward mutual-recognition filings in Guatemala, Honduras, or Nicaragua.

Section A. Regulator profile

Name: *Superintendencia de Regulación Sanitaria* (Superintendency of Health Regulation), SRS — successor authority to the *Dirección Nacional de Medicamentos* (DNM). The SRS is an autonomous public-law institution with technical character, its own legal personality and patrimony, and full financial, administrative, and budgetary autonomy (SRS Ley Art. 1).

Establishing statute: *Ley de la Superintendencia de Regulación Sanitaria*, Legislative Decree No. 891 of 30 November 2023, reformed by Legislative Decree No. 30 of 19 June 2024 (published in the Diario Oficial No. 129, Tomo 444, on 8 July 2024). The Ley entered into force on 7 August 2024. Article 39-A grants a 120-business-day dissolution period for the DNM to ensure uninterrupted continuity of pending files (SRS Ley Arts. 1, 3, 39-A, 46; LatinAlliance). The underlying substantive statute — the *Ley de Medicamentos*, Decreto Legislativo No. 1008 of 22 February 2012 (Diario Oficial No. 43, Tomo No. 394, 2 March 2012) — and its General Regulation (Decreto Legislativo No. 245, Diario Oficial No. 239, Tomo No. 397, 20 December 2012) remain the operative technical laws for medicines and medical devices (Ley de Medicamentos; RTS 11.03.02:21 §§7.2–7.3).

Scope: The SRS is *the State authority responsible for regulating, monitoring and granting sanitary registration, registration recognition, marketing authorization and their modifications and renewals, and import, export and certification permits for pharmaceutical products, medicines, nutritional supplements, medical devices and equipment, other health technologies, cosmetics, hygienics, chemicals, foods, beverages, alcohol, tobacco, nicotine-release devices, and related products for human and veterinary use* (SRS Ley Art. 3).

Website: https://www.srs.gob.sv

Headquarters address: *Blv. Merliot y Av. Jayaque, Edif. SRS, Urb. Jardines del Volcán, Santa Tecla, La Libertad Sur, La Libertad.* Phone: (+503) 2522-5000 (SRS).

Current head of authority: *Superintendente de Regulación Sanitaria* — MSc. Noé Geovanni García Iraheta (appointed 31 January 2025) (Portal de Transparencia).

Adjacent bodies sharing responsibility. El Salvador's post-August-2024 architecture is intentionally centralized in the SRS. Two adjacent bodies retain jurisdiction over clinical research.

Body	Role	Reference
Consejo Superior de Salud Pública (CSSP) — Paseo General Escalón #3551, San Salvador	*Autoridad de Vigilancia Nacional del Cumplimiento de las Buenas Prácticas Clínicas*; hosts the CNEIS and inspects research centers	Manual CNEIS
Comité Nacional de Ética de Investigación en Salud (CNEIS)	National ethics committee; reviews and approves clinical-trial protocols and ICFs; accredits local CEIC/CEIS committees; anchored in the Constitution Arts. 69 y 79 and Ley de Medicamentos Art. 66	Manual CNEIS
SRS — Unidad de Ensayos Clínicos (successor to DNM's role)	Authorizes clinical trials, authorizes substantial amendments, authorizes import of investigational product, inspects trials, may suspend or halt studies	RTS 11.03.02:21 §6.1; SRS Agenda Regulatoria 2025
Ministerio de Salud (MINSAL) / Centro Nacional de Farmacovigilancia (CNFV)	Coordinates the Sistema Nacional de Farmacovigilancia under RTS 11.02.02:16; SRS remains audit and enforcement arm	RTS 11.02.02:16 §§6.1–6.3; Lineamientos FV 2025
Ministerio de Relaciones Exteriores (RREE)	Sole authority to issue apostilles for Salvadoran documents; validates legalizations for foreign documents from non-Hague countries	RREE Auténticas y Apostillas

Body	Role	Reference
OSARTEC — Organismo Salvadoreño de Reglamentación Técnica	Publishes RTS and RTCA Salvadoran-side texts	OSARTEC

Section B. Official language requirements

El Salvador's rule is the most surgically narrow of the Big 7 on Spanish translation of technical documents, and the most expansive on Spanish-language labelling and IFU.

Statutory anchor — RTS 11.03.02:21 §6.3.4.d (verbatim, medical devices):

> *"El etiquetado del empaque primario debe presentarse en idioma castellano o mediante simbología conforme a la norma ISO 15223-1, en su versión vigente."*

The primary-package label must be in castellano *or* via ISO 15223-1 symbology, in its current version (RTS 11.03.02:21 §6.3.4.d).

Statutory anchor — RTS 11.03.02:21 §6.4.3.e (verbatim, used biomedical equipment):

> *"El fabricante debe suministrar al usuario los manuales de operación, instalación y mantenimiento en el idioma de origen y en castellano."*

For used, remanufactured, or reconditioned biomedical equipment, the manufacturer must supply operation, installation, and maintenance manuals in both the source language and castellano (RTS 11.03.02:21 §6.4.3.e).

Statutory anchor — Manual CNEIS (verbatim, clinical trials):

> *"Si el original está escrito en otro idioma: debe presentarse el protocolo traducido al español; la versión en español debe incluir la fecha de edición; deben entregarse tres copias impresas y una copia electrónica de la versión en español."*

Foreign-language protocols must be filed with a complete Spanish translation, three printed copies, one electronic copy, and the Spanish version must carry its own edition date (Manual CNEIS).

Two doctrinal facts embedded in the framework. First, castellano is a labelling and IFU rule, not a general dossier translation rule. RTS 11.03.02:21 explicitly does *not* state that all foreign technical documents in a medical-device registration dossier must be translated to Spanish, and the RTS on pharmacovigilance (RTS 11.02.02:16) is silent on any general Spanish-translation obligation (RTS 11.02.02:16 §§100–104). Second, for clinical trials, the ethics committee (CNEIS) applies a bifurcated rule: the *investigator's brochure* can remain in its original language accompanied by a Spanish summary, but the *protocol and the ICF must be fully translated to Spanish and adapted to the reading level of the subject population — not literally translated* (Manual CNEIS).

Drug labelling — RTCA 11.01.02:04 (verbatim requirement). The Central American Technical Regulation on drug labelling — RTCA 11.01.02:04 (Resolution 275-2011 COMIECO-LXI, modified by Resolution 340-2014) — governs labelling of pharmaceutical products marketed in El Salvador. Labelling must be in castellano; imported products' labels may include the source language in addition to castellano, but the Spanish text is the reference version for inspection and enforcement (SRS RTCA; Resolución 166-2006 modificatoria).

Drug registration dossier — RTCA 11.03.59:18. The Central American Technical Regulation *Productos Farmacéuticos. Medicamentos para Uso Humano. Requisitos de Registro Sanitario* (Resolution 446-2021 COMIECO-XCIV of 14 June 2021, in force) governs the sanitary-registration dossier composition and Mutual Recognition procedures across the six Central American member states. It is the *substantive* dossier standard applied by the SRS (SRS RTCA; Lexology summary).

Clinical-trial language table (medical devices — RTS 11.03.02:21 §§6.1–6.3.4; drugs — Manual CNEIS + Ley de Medicamentos Art. 66).

Document	Language rule	Statutory anchor
Protocol (original)	Original language (may be English)	Manual CNEIS
Protocol (Spanish)	Full Spanish translation with own edition date; 3 hard + 1 electronic copy	Manual CNEIS
Informed consent form (ICF)	Bilingual filing: original + Spanish; Spanish must be adapted to subject reading level, not a literal translation, ≤2 pages, plain language, tested for comprehension with non-medical readers	Manual CNEIS
Investigator's brochure	Original language + Spanish summary (not full translation)	Manual CNEIS Anexo 2

Document	Language rule	Statutory anchor
Insurance certificate for participants	Original + Spanish translation certified by translator; must specify coverage and mechanism of applicability in El Salvador	Manual CNEIS
Investigator CVs, GCP evidence	Not expressly required in Spanish	Manual CNEIS
Amendments	New version numbers + new dates; changes marked; prior and revised texts both filed	Manual CNEIS Anexo 11A
Device primary-package label	Castellano *or* ISO 15223-1 symbology	RTS 11.03.02:21 §6.3.4.d
Device IFU / manuals for used biomedical equipment	Source language and castellano	RTS 11.03.02:21 §6.4.3.e
Foreign legal-administrative documents (CFS, CPP, GMP certificates, powers of attorney, apostilles)	Must be legalized per national norms; SRS practice (inherited from DNM guide C02-RS-01-UR_PF.GUI01 v06 §5) is to require *traducción oficial* for these legal instruments	RTS 11.03.02:21 §6.3.2.1; DNM/SRS practice

The regime is layered by document type, not by document age. Unlike Peru (two-year currency rule) or Colombia (INVIMA one-year rule for CFS), El Salvador's technical regulations do not impose a fixed calendar-day currency limit — but Salvadoran practice requires the underlying Certificate of Free Sale, CPP, and GMP certificate to be current and free of alerts, and the SRS may reject stale filings under Ley de Medicamentos general provisions on sanitary safety (RTS 11.03.02:21 §6.4.1).

Section C. Sworn vs certified vs simple translation

**El Salvador reserves* traducción oficial *— sworn translation — for legal-administrative instruments, not technical evidence. The pharmaceutical registration guide C02-RS-01-UR_PF.GUI01 v06 (published by the DNM and inherited by the SRS Unidad de Registro de Productos Farmacéuticos) states in §5 that* traducción oficial* is reserved for documents such as the Carta de Representación, apostilles, and foreign certificates of authority. Technical documents (clinical evaluation reports, risk-management reports, stability studies, validation reports) do not require sworn translation, though many are subject to castellano-labelling or IFU obligations under RTS 11.03.02:21 (DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5).

Tier table.

Tier	Salvadoran designation	When it applies	Who certifies
Sworn / official	*Traducción oficial*	Foreign legal-administrative documents: Carta de Representación, apostilles, powers of attorney, foreign CPP, foreign GMP certificate, foreign CFS, sponsor delegation of authority for clinical trials, insurance certificates for participants	Authorized Salvadoran official translator (translator whose credentials are recognized by the Ministerio de Relaciones Exteriores); embassy-recognized translator lists (US Embassy publishes a reference list for Salvadoran use) (US Embassy — Traductores; ClaudiaRamirezTranslator)
Certified	*Traducción certificada por el traductor*	Insurance certificate for participants in clinical trials (Manual CNEIS explicit rule); other clinical-trial supporting documents where explicit certification is requested	Translator with attestation of credentials and signed certification statement
Simple	*Traducción al español*	Protocol (Spanish version), ICF (Spanish version, subject-adapted), technical documents where castellano labelling or IFU applies (device labels, manuals of used biomedical equipment)	Sponsor / CRO — no sworn translator required

Apostille sequencing. El Salvador acceded to the Hague Apostille Convention. Documents issued in a Hague-Convention country must be apostilled by that country's competent authority before entering El Salvador; documents from non-Hague countries require *auténtica* through El Salvador's diplomatic and consular representations (RREE). Salvadoran documents destined for foreign use are apostilled free of charge by the *Ministerio de Relaciones Exteriores* — the sole issuing authority — and take immediate effect in any Hague-Convention country without further consular processing (RREE).

The sequencing rule that trips foreign sponsors: the foreign document must be apostilled in its country of origin, then translated in El Salvador by an authorized official translator. Translating first and then apostilling the translation does not create an apostilled *foreign document* — it creates an apostilled *Salvadoran translation*, and the underlying foreign public document remains unauthenticated. Sponsors filing in El Salvador must apostille first, translate second, and file both together.

Amavita's 7th QC gate — Document Currency. El Salvador is the LATAM jurisdiction where currency risk is most operationally unpredictable, because two structural facts stack on top of each other. First, the SRS is still consolidating DNM legacy files under a 120-business-day dissolution rule (LatinAlliance) — an apostille or CFS obtained during the transition may face jurisdictional questions if presented to the successor unit. Second, RTS 11.03.02:21 does not specify calendar-day review timelines, meaning a dossier can sit in queue while its underlying foreign documents age. Amavita's Document Currency gate captures both: it timestamps every foreign document at apostille, at translation, and at filing, and re-issues a fresh translation within 48 hours if the sponsor's apostilled document is refreshed under the 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 (for devices), and their appendices. El Salvador operates within the Central American RTCA harmonized regime (RTCA 11.03.59:18 for drugs, RTCA 11.03.63:19 device references), and its language surface is the narrowest in LATAM — castellano is mandatory only for device labels (RTS 11.03.02:21 §6.3.4.d — or ISO 15223-1 symbology), used biomedical equipment IFU (§6.4.3.e), and clinical-trial protocols/ICFs (Manual CNEIS). The rest of the preclinical stack has significant flexibility.

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

No. SRS/DNM's Amavita-verified position:

- Drugs under RTCA 11.03.59:18: Central American harmonized regime with Anexo 2 Mutual Recognition across Guatemala, Honduras, Nicaragua, Costa Rica, and Panama — a compliant SRS drug dossier becomes a regional launchpad. Preclinical modules follow CTD structure; Spanish is preferred but reviewers accept English technical annexes at the SRS level, with Spanish executive summaries.
- Devices under RTS 11.03.02:21: §6.3.4.d permits castellano OR ISO 15223-1 symbology on medical-device primary labels. §6.4.3.e requires bilingual manuals only for used biomedical equipment IFU. Sponsor-generated preclinical (biocompatibility, sterility, stability, risk analysis, electrical safety) is treated as technical documentation, not as *traducción oficial*-scoped material.
- Traducción oficial is reserved for legal-administrative documents under DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5 — not for study-report bodies.
- Clinical trials under Manual CNEIS: Spanish protocol/ICF is mandatory; investigator's brochure accepted in source language with a Spanish summary.

- PAHO Level IV reliance: RTS §6.1.4(a) allows recognition of decisions from PAHO/WHO Level IV-certified agencies and high-surveillance agencies — the substrate for accepting foreign preclinical review letters with reduced translation burden.

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

Document class	Translation scope	DTP (visual replication) required?
GLP study-report body text, discussion, methods, tables	Full Spanish executive summary; original English body accepted at SRS technical tier	No — text-flow for the Spanish summary
GLP study-report figures, plots, chromatograms, gels	No translation — original artwork stands	No
Foreign health-authority preclinical review letters (from PAHO Level IV agencies under RTS §6.1.4(a))	**Spanish* — traducción oficial*** per DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5	Yes — mirror letterhead, seals, signature block
Foreign GMP certificate, CFS, CPP	**Spanish* — traducción oficial + *apostille** (El Salvador acceded to Hague Apostille Convention 2019)	Yes — mirror seals and page numbering
Device primary label	Castellano OR ISO 15223-1 symbology (RTS 11.03.02:21 §6.3.4.d)	Yes if castellano text is elected; No if symbology is elected
Device IFU	Castellano for new equipment; bilingual for used biomedical equipment (RTS §6.4.3.e)	Yes — regulatory DTP
Clinical protocol (CNEIS)	Full Spanish (Manual CNEIS)	Ethics-committee formatted
Investigator's Brochure	Source language accepted with Spanish summary (Manual CNEIS)	Text-flow for the Spanish summary
Informed Consent Form (ICF)	Full Spanish — site-specific, CNEIS-approved	Yes — mirror CNEIS-approved template
Drug labelling and package insert (RTCA 11.03.59:18)	Full Spanish; Anexo 2 Mutual Recognition allows single regional master with country-specific overlays	Yes — regulatory DTP

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

El Salvador's answer is the most flexible in the region for device preclinical because of the ISO 15223-1 symbology substitution at §6.3.4.d. Amavita's recommended format:

For drugs (RTCA 11.03.59:18 regional dossier):

1. Original English CTD Modules 3, 4, and 5 — accepted at SRS technical tier for the initial dossier body.
2. Full Spanish CTD Module 2 (Quality Overall Summary, Non-clinical Overview 2.4, Non-clinical Written & Tabulated Summaries 2.6, Clinical Overview 2.5, Clinical Summary 2.7). This is the operational Spanish deliverable that carries reviewer read-time.
3. Full Spanish CTD Module 1 — country wrapper, always Spanish.
4. RTCA Anexo 2 Mutual Recognition packet — if the sponsor plans to file across Central America, the SRS-approved Spanish Module 2 + Module 1 becomes the reusable regional artifact for Guatemala, Honduras, Nicaragua, Costa Rica, and Panama.

For devices (RTS 11.03.02:21):

1. Original English biocompatibility, sterility, stability, risk analysis, electrical-safety reports — accepted at SRS technical tier.
2. Per-study Spanish executive summary (1–3 pages) at the front of each technical report — method (ISO cite), test conditions, key results, pass/fail conclusion.
3. Consolidated Spanish technical summary cross-referencing every ISO report by study number and page.
4. ISO 15223-1 symbology on primary labels for the device label — elects symbology in place of castellano text under §6.3.4.d, eliminating one of the highest-volume DTP tasks in the dossier.
5. Castellano IFU for new equipment; bilingual IFU for used biomedical equipment per §6.4.3.e.

For clinical trials (Manual CNEIS):

1. Full Spanish protocol — mandatory.
2. Full Spanish ICF — mandatory, CNEIS-approved.
3. Investigator's Brochure in source language + Spanish summary — the operational escape valve for IB translation cost, unique to CNEIS in LATAM.

The two regulatory pathways trigger different translation obligations

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

Pathway 1 — clinical-trial authorization

- Under Manual CNEIS, protocol and ICF must be full castellano and adapted to the subject's reading level.

- IB accepted in source language with a Spanish summary.
- Foreign health-authority letters as traducción oficial + apostille per DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5.

Pathway 2 — market-access / sanitary registration

- Device primary label in castellano or ISO 15223-1 symbology per RTS 11.03.02:21 §6.3.4.d (DTP required if castellano text is elected; not required if symbology is elected).
- Device IFU / manuals: castellano for new equipment; source language and castellano for used, remanufactured, or reconditioned biomedical equipment per RTS §6.4.3.e (DTP required).
- Drug labelling in castellano per RTCA 11.03.59:18 (with Anexo 2 Mutual Recognition allowing a regional master + country overlays across CA-6).

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

D.4 Consolidated preclinical instruction table

Preclinical document	Language	Translation type	DTP?	Endorsement	Apostille?
CTD Module 3 (CMC/quality)	English accepted at SRS tier	Spanish executive summary	Text-flow	Sponsor QA	No
CTD Module 4 (non-clinical study reports)	English accepted at SRS tier	Spanish executive summary	Text-flow	Sponsor QA	No
CTD Module 5 (clinical study reports)	English accepted at SRS tier	Spanish executive summary	Text-flow	Sponsor QA	No
CTD Module 2 (summaries, overviews)	Spanish	Traducción simple, full	Text-flow only	Sponsor QA	No
CTD Module 1 (administrative wrapper)	Spanish	Traducción simple, full	Text-flow; DTP for label mock-ups	Sponsor QA	No
GLP figures, chromatograms, gels	Original language	No translation	No	—	No

Preclinical document	Language	Translation type	DTP?	Endorsement	Apostille?
Device biocompatibility / sterility / stability / risk analysis / EMC	English accepted; Spanish summary	Traducción simple (summary only)	Text-flow	Sponsor QA	No
Device primary label	Castellano OR ISO 15223-1 symbology (§6.3.4.d)	Full Spanish if elected; symbology if not	Yes for castellano	Sponsor QA	No
Device IFU (new equipment)	Castellano	Full Spanish	Yes — regulatory DTP	Sponsor QA	No
Device IFU (used biomedical equipment)	Bilingual (§6.4.3.e)	Full Spanish + source language	Yes — regulatory DTP	Sponsor QA	No
Investigator's Brochure (CNEIS)	Source language + Spanish summary	Manual CNEIS: source + Spanish summary	Text-flow for summary	Sponsor QA	No
Clinical protocol (CNEIS)	Spanish	Full Spanish, mandatory	Ethics-committee formatted	Sponsor QA	No
ICF (CNEIS)	Spanish	Full Spanish, mandatory	Yes — mirror CNEIS template	Site + CNEIS	No
Foreign health-authority preclinical review letter	Spanish	*Traducción oficial* (DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5)	Yes — mirror seals	Traductor oficial	Yes
Foreign GMP certificate, CFS, CPP	Spanish	*Traducción oficial*	Yes	Traductor oficial	Yes
Drug labelling and package insert (RTCA 11.03.59:18)	Spanish	Full Spanish; Anexo 2 regional master + overlays	Yes — regulatory DTP	Sponsor QA	No

D.5 Where the preclinical translation risk actually sits

The common defect is conflating traducción oficial scope with technical-document scope. Sponsors sometimes pay for *traducción oficial* of biocompatibility reports (unnecessary; SRS

accepts them in English with Spanish summary) or file legal-administrative documents with only a sponsor-QA-signed translation (insufficient; DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5 requires *traducción oficial* for legal-administrative documents). The device-label symbology option under §6.3.4.d is the single largest cost reducer in the SRS translation surface and is routinely under-elected.

CONSULTA PENDING

Consulta filed with SRS — Unidad de Ensayos Clínicos (El Salvador)

Filed: 24 August 2026

Follow-up sent: 25 August 2026 (courtesy nudge with delivery-receipt confirmation)

Filed with: ensayos.clinicos@srs.gob.sv

Question filed: Formal confirmation of the preclinical translation scope required at CTA stage under RTS 11.03.02:21 §§7.2–7.3 and the Manual CNEIS bifurcated-language rule, including whether English IB accompanied by Spanish summary satisfies the SRS + CNEIS reviewers when the protocol is filed in full Spanish translation.

Amavita Sciences™ has filed a formal consulta with SRS — Unidad de Ensayos Clínicos (in coordination with CNEIS, CSSP) at ensayos.clinicos@srs.gob.sv on 24 August 2026. The question submitted is: “Formal confirmation of the preclinical translation scope required at CTA stage under RTS 11.03.02:21 §§7.2–7.3 and the Manual CNEIS bifurcated-language rule, including whether English IB accompanied by Spanish summary satisfies the SRS + CNEIS reviewers when the protocol is filed in full Spanish translation.”. This section will be revised upon receipt of a written response. Sponsors filing before the response arrives should assume the strict reading: full traducción simple of the preclinical stack for CTA-stage submissions.

CATEGORY 1: DRUGS

D1. Drug market access — SRS pathway

Governing instruments.

- *Ley de Medicamentos* — Decreto Legislativo No. 1008 (2 March 2012) (Ley de Medicamentos)
- *Reglamento General de la Ley de Medicamentos* — Decreto Legislativo No. 245 (20 December 2012)
- RTCA 11.03.59:18 — Productos Farmacéuticos. Medicamentos para Uso Humano. Requisitos de Registro Sanitario (Resolution 446-2021 COMIECO-XCIV, in force) (SRS RTCA)
- RTCA 11.01.02:04 — Etiquetado de Productos Farmacéuticos para Uso Humano
- RTCA 11.03.42:07 — Buenas Prácticas de Manufactura para la Industria Farmacéutica
- RTS 11.02.02:16 — Farmacovigilancia
- DNM guide C02-RS-01-UR_PF.GUI01 v06 — Requisitos para Registro Sanitario Farmacéutico (procedural guide inherited by the SRS Unidad de Registro de Productos Farmacéuticos)

Registration modalities under RTCA 11.03.59:18.

Modality	When it applies	Reference
Registro sanitario — full national registration	New products entering the Salvadoran market without an existing Central American registration	RTCA 11.03.59:18
Reconocimiento Mutuo (Anexo 2 of Resolution 446-2021)	Products already holding a sanitary registration in another RTCA member state (Guatemala, Honduras, Nicaragua, Costa Rica, Panama); El Salvador recognizes the source-country registration under harmonized criteria	RTCA 11.03.59:18 Anexo 2; SRS RTCA
Registro sanitario abreviado for orphan drugs and unavailable-in-market products	Ley Especial de Precios exempts these from certain fees	LEPS-DNM

Language and translation stack.

- Product labelling: castellano — mandatory under RTCA 11.01.02:04.
- Insert / prospecto: castellano — mandatory under RTCA 11.01.02:04.
- **Foreign CPP, CFS, GMP certificate: apostilled +* traducción oficial*** — required under DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5.
- **Carta de Representación from foreign manufacturer to Salvadoran importer: apostilled +* traducción oficial.*
- Stability studies, analytical validation, technical file: castellano recommended but the RTCA does not mandate sworn translation.

Fees under Ley Especial de Precios (LEPS-DNM, in force from 1 January 2024 — inherited by the SRS).

Item	Fee (USD)	Source
Sanitary registration / renewal — drugs	Variable by class; general drug registration fee published by SRS	LEPS-DNM
Sanitary registration — medical devices (1–25 codes)	$150.00	LEPS-DNM §3.1.1
26–100 codes	$360.00	LEPS-DNM §3.1.2
101–500 codes	$720.00	LEPS-DNM §3.1.3
501–1000 codes	$1,080.00	LEPS-DNM §3.1.4
1001+ codes	$1,440.00	LEPS-DNM §3.1.5
Antiseptics / disinfectants / sutures / tubes	$750.00	LEPS-DNM §6.2.1
Public institutions (including ISSS)	Exempt	LEPS-DNM Art. 2
Orphan drugs, patient-requested unavailable products	Exempt	LEPS-DNM Art. 2

Reliance / recognition. Under RTS 11.03.02:21 §6.1.4(a), the SRS (formerly DNM) *may recognize and use decisions, requirements, reports, or information issued by health authorities of countries whose drug regulatory agencies have been certified as level IV by PAHO/WHO*, and* may recognize clinical trials authorized by high-surveillance agencies and by PAHO/WHO* (IMDRF — SRS El Salvador presentation). This reliance clause is one of the broadest in Central America and is often decisive for Latin-American filings by U.S., E.U., and Japanese sponsors.

D2. Drug regulatory submissions

Base dossier (RTCA 11.03.59:18 + DNM/SRS procedural guide).

1. Mandamiento de pago (proof of paid fees under LEPS-DNM)
2. Registration form
3. Certificate of Free Sale (CFS) — apostilled + *traducción oficial*
4. Certificate of Pharmaceutical Product (CPP) — apostilled + *traducción oficial*
5. Good Manufacturing Practices certificate — apostilled + *traducción oficial*
6. Manufacturing contract (if applicable)
7. Product technical file (quality, stability, bioequivalence when applicable)
8. Primary-package label proof — castellano
9. Secondary-package label proof — castellano
10. Insert / prospecto — castellano
11. Carta de Representación (foreign manufacturer → Salvadoran importer) — apostilled + *traducción oficial*

12. Analytical validation report
13. Stability study
14. Sample of finished product for quality control by SRS laboratory (where applicable)

Post-registration modifications. The SRS's 2025 regulatory agenda (AR-SRS-005) commits to publishing a *Guía para trámites de modificaciones jurídicas posteriores al registro sanitario de productos regulados por la SRS* in September 2025, and AR-SRS-002 covers device-specific post-registration modifications (SRS Agenda 2025). Until publication, DNM legacy procedures continue.

Renewal cadence. Sanitary registrations are valid for 5 years, must be renewed 6 months before expiry or up to 3 months after expiry — after which suspension and cancellation proceedings begin (RTS 11.03.02:21 §6.3.1.f). Annual fees (anualidad) must be paid to keep the registration active (RTS 11.03.02:21 §6.3.1.g).

Pharmacovigilance obligations. Under RTS 11.02.02:16 (Acuerdo 1529, in force from 17 October 2016), sanitary-registration holders must:

- Cooperate with the Centro Nacional de Farmacovigilancia (CNFV, dependent on MINSAL) (RTS 11.02.02:16 §6.2)
- Submit *Informes Periódicos de Seguridad* (IPS/PSUR/PBRER) when required as a condition of marketing authorization (SRS trámite IPS/PSUR/PBRER)
- Notify serious adverse reactions (RAM Graves) per the *Lineamientos Técnicos de Farmacovigilancia* (Acuerdo Ejecutivo AE-3111 of 22 December 2025) (Lineamientos FV 2025)
- Hold and demonstrate compliance with a Certificate of Good Pharmacovigilance Practices when required by the SRS (RTS 11.02.02:16 §6.3.6)
- File Plan de Gestión de Riesgos (Risk Management Plan) for new medicines (SRS trámite PGR)

D3. Drug clinical trials

Authorization architecture. El Salvador applies a dual-authorization model: ethics review by the CNEIS (national) or an accredited local CEIC/CEIS, and regulatory authorization by the SRS (formerly DNM). Ley de Medicamentos Art. 66 is the primary statutory anchor (Manual CNEIS).

Filing dossier for CNEIS review. Per the Manual CNEIS:

- Carta de intención
- Center authorization (signed by health-center authority)
- Full protocol in original language + Spanish translation (3 hard + 1 electronic copy)
- ICF in original + Spanish (adapted to subject reading level, ≤2 pages, plain language, tested for comprehension)
- Investigator's brochure (original + Spanish summary)

- Product information
- GCP training certifications
- Health insurance certificate for participants — original + Spanish translation certified by translator + statement of coverage mechanism in El Salvador
- Principal investigator CV + co-investigator CVs
- Evidence of GCP training
- Sponsor-investigator payment documentation
- Proof of arancel payment when applicable
- Annex 2 checklist + drug evaluation form

CNEIS review timelines.

- Full pleno evaluation (studies with more than minimal risk): reviewers submit written evaluations electronically within 4 to 6 weeks (Manual CNEIS)
- Expedited evaluation (minimal-risk studies, minor amendments): reviewers submit within 7 days
- Studies whose sole purpose is to evaluate a specific program (not generalizable knowledge) do not require ethics review

Decision categories.

- Aprobado sin restricciones (ASR)
- Falta Información (FI) — approved with observations and requested amendments
- No aprobado (PRT / RCT) — rejected for technical or ethical reasons

SRS regulatory authorization (post-DNM). RTS 11.03.02:21 §6.1 grants the SRS (via its Unidad de Ensayos Clínicos) authority to:

- Authorize the clinical trial itself
- Authorize substantial amendments before implementation
- Authorize importation of the investigational product
- Inspect trial sites
- Suspend or halt trials for clinical, technical, or legal reasons
- Recognize clinical trials authorized by *high-surveillance* agencies and by PAHO/WHO (§6.1.4.a)

SRS 2025 regulatory agenda commitments (still in adoption pipeline as of August 2026 — status varies by item):

- AR-SRS-009 — *Guía de Buenas Prácticas Clínicas* (adoption target: June 2025)
- AR-SRS-012 — *Regulación de ensayos clínicos* (adoption target: July 2025)

These will supersede legacy DNM guidance once formally in force (SRS Agenda Regulatoria 2025). El Salvador is also currently debating a comprehensive *Ley de Ensayos Clínicos*, with the *Comisión de Salud* of the Asamblea Legislativa having approved a project in 2025 (El Salvador — Comisión de Salud).

Adverse-event reporting. Adverse events during a clinical trial must be reported to both the CNEIS/CEIC and the SRS during the investigation and until the period stipulated in the protocol (RTS 11.03.02:21 §6.1.1.h). Serious adverse reactions in commercialized drugs are notified under the *Lineamientos Técnicos de Farmacovigilancia* (2025).

CATEGORY 2: MEDICAL DEVICES

E1. Device market access — SRS pathway

Governing instruments.

- *Ley de Medicamentos* — Decreto Legislativo No. 1008
- RTS 11.03.02:21 — Dispositivos Médicos. Requisitos para la Regulación Sanitaria de Dispositivos Médicos (in force 6 months after publication, per §10) (RTS 11.03.02:21)
- RTS 11.03.03:22 — Dispositivos Médicos. Buenas Prácticas de Manufactura de Dispositivos Médicos y su guía de verificación (based on ISO 13485:2016) (IMDRF — SRS)
- RTS 11.03.04:23 — Vigilancia Poscomercialización de Dispositivos Médicos. Tecnovigilancia

Classification (RTS 11.03.02:21 §6.3.1.a). Four risk classes, harmonized with GHTF and IMDRF principles.

Class	Risk level	Characteristics
Class A	Low	Not intended to protect or sustain life, not of critical importance in preventing health deterioration, no unreasonable potential risk
Class B	Low-moderate	Subject to special manufacturing controls to demonstrate quality, safety, and efficacy
Class C	Moderate-high	Subject to special manufacturing controls

Class	Risk level	Characteristics
Class D	High	Special controls; devices that protect or sustain life, substantially important in preventing health deterioration, or with meaningful potential for illness or injury

Nature-based additional categories: IVDs, antiseptics/disinfectants for medical-hospital use, Software as Medical Device (SaMD), other devices.

E2. Device regulatory submissions

Base dossier (RTS 11.03.02:21 §6.3.2.1).

1. Mandamiento de pago
2. Device registration form
3. Certificate of Free Sale (CFS) — apostilled + *traducción oficial* recommended per DNM legacy guide
4. GMP certificate — apostilled + *traducción oficial* recommended
5. Quality-control specifications for the device
6. Manufacturing / maquila contract (if applicable)
7. Device technical sheet
8. Technical information of the medical device
9. Primary-package label proof — castellano or ISO 15223-1 symbology
10. Secondary-package label proof — castellano or ISO 15223-1 symbology
11. Risk-management report
12. Safety report and sanitary alerts report

Category-specific additions (RTS 11.03.02:21 §6.3.2.2–.5).

- IVDs (§6.3.2.2): IFU/insert, shelf-life/stability technical document, storage/transport conditions, cuali-cuantitative formula, safety data sheet, validation reports
- SaMD (§6.3.2.3): Components/accessories diagram, technical design report, cybersecurity/storage/communication report, verification-and-validation testing report, version history (resolved and unresolved anomalies/errors), obsolescence timeline, clinical-evaluation studies when applicable
- Antiseptics / disinfectants (§6.3.2.4): Insert, shelf-life, storage/transport, cuali-cuantitative formula, sterilization certificate (when applicable), container-closure document, MINSAL alcohol registration document, MINSAL alcohol quota document, effectiveness validation

- Other devices (§6.3.2.5): Components/accessories diagram (when applicable), insert (when applicable), shelf-life, storage/transport, cuali-cuantitative formula (when applicable), sterilization certificate (when applicable), drug-manufacturer GMP (for combination devices), safety data sheet (when applicable), clinical-evaluation studies

Language and translation stack — devices.

- Labels: castellano or ISO 15223-1 symbology (RTS §6.3.4.d)
- IFU / manuals for used, remanufactured, or reconditioned biomedical equipment: castellano + source language (RTS §6.4.3.e)
- Technical documents (design reports, cybersecurity reports, validation, clinical evaluation): no explicit Spanish translation requirement in the RTS
- **Foreign legal-administrative documents (CFS, GMP, manufacturing contracts, powers of attorney): must be legalized per national norms (RTS §6.3.2.1); Salvadoran practice — inherited from DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5 — requires apostille +* traducción oficial***

Validity, renewal, anualidad (RTS §§6.3.1.f–g).

- Validity: 5 years
- Renewal window: 6 months before expiry to 3 months after expiry
- Annual fee (anualidad) required to keep registration active
- Suspension + cancellation if renewal window closes without payment

Import requirements (RTS §6.4.1).

- Active sanitary registration
- Solvent anualidad
- Valid renewal
- Registered and solvent-anualidad importer
- Minimum 6 months to expiry for the imported product
- Absence of active sanitary alerts
- Original + copy of factura signed and stamped by Profesional Responsable and importing establishment
- Certificate of batch-release analysis available for sanitary inspection

Special import (RTS §6.4.2). Applies to devices for scientific research (with CNEIS-approved protocol + SRS favorable opinion), OPS/OMS procurements, personal or business use, product samples, diplomatic use, national health system use, donations, and public-health emergencies.

Essential principles of safety and performance (RTS §§5.2.1–5.2.2, aligned with WHO framework). The SRS may verify manufacturer compliance before, during, and after market introduction

through technical documentation, sanitary inspections, or other evaluations deemed necessary (IMDRF — SRS El Salvador).

Post-market surveillance — tecnovigilancia (RTS 11.03.04:23). Every establishment must designate a *Referente de Tecnovigilancia* responsible for identification, registration, evaluation, management, follow-up, and timely disclosure of adverse events and incidents (RTS 11.03.02:21 §3.36, §6.2.1.b).

E3. Device clinical trials

The clinical-trial framework for medical devices operates under the same dual-authorization model (CNEIS ethics + SRS regulatory) with device-specific additions in RTS 11.03.02:21 §§6.1.1–6.1.3. Key sponsor obligations:

- Provide attestations of compliance with a quality-management system for device production (typically ISO 13485)
- Provide handling, storage, and disposal specifications
- Provide the investigator's brochure and protocol
- Declare quantities of investigational product and auxiliary products with justification tied to intervention type and patient number
- Notify deviations, adverse events, and incidents during the study
- At study end, notify for supervision of disposal of remaining, returned, or expired product
- Maintain inventory-control documentation
- Destroy investigational product per SRS procedures

The SRS's *Unidad de Ensayos Clínicos* is the successor operational unit; its 2025 regulatory agenda commitments (AR-SRS-009, AR-SRS-012) apply to both drugs and devices (SRS Agenda Regulatoria 2025).

Section F. Common RFI / rejection patterns

Amavita's six defect classes mapped onto El Salvador's statutory surfaces. Each rejection pattern below is a live SRS/DNM-legacy failure mode observed in Salvadoran filings.

Defect class	El Salvador surface	RFI/rejection example
Currency defect	Foreign CFS, CPP, GMP certificate — no fixed RTS calendar limit but stale documents rejected under sanitary-safety discretion	*"La documentación de respaldo presenta antigüedad no razonable en relación con el producto solicitado; presente CFS actualizado."*
Legalization / apostille chain defect	Foreign document translated before apostille; apostille from non-Hague jurisdiction; unrecognized translator	*"El documento extranjero no cumple con la legalización establecida en 6.3.2.1 del RTS 11.03.02:21; presente apostilla o auténtica según país de origen."*
Castellano labelling defect	Primary-package label in source language only, no ISO 15223-1 symbology fallback	*"Las etiquetas presentadas no cumplen con el idioma castellano ni con simbología ISO 15223-1 vigente; corrija conforme a 6.3.4.d."*
Used-equipment IFU defect	Used biomedical equipment IFU/manuals filed only in source language	*"Los manuales de operación deben suministrarse en el idioma de origen y en castellano conforme a 6.4.3.e; presente versión bilingüe."*
Trial protocol translation defect	Spanish protocol missing edition date, insufficient copies filed with CNEIS, or ICF as literal translation not adapted to subject reading level	*"El protocolo en español debe incluir fecha de edición; la versión del consentimiento informado debe adaptarse al lenguaje de los sujetos, no ser traducción literal."*
Transition / jurisdiction defect	Documents addressed to DNM after 7 August 2024 without SRS successor recognition	SRS practice: dossier must be re-addressed to SRS with reference to the appropriate Unidad (Registro de Productos Farmacéuticos / Registro de Dispositivos Médicos / Ensayos Clínicos); DNM legacy files in process are automatically transitioned during the 120-business-day dissolution window (LatinAlliance)

Section G. Consolidated timelines

Sub-category	Procedure	Statutory timeline	Empirical / practical	Source
Drugs — sanitary registration	Full national registration	Not fixed in calendar days by RTCA 11.03.59:18	Typically 6–12 months depending on completeness	RTCA 11.03.59:18; DNM/SRS practice
Drugs — Mutual Recognition	Anexo 2 Reconocimiento Mutuo procedure	Not fixed in calendar days	Materially faster than full national registration when source-country registration is documented	SRS RTCA
Drugs — renewal window	6 months before expiry to 3 months after	5-year registration validity	Late renewal triggers suspension + cancellation	RTS 11.03.02:21 §6.3.1.f (analogous rule applied to drugs)
Devices — sanitary registration	RTS 11.03.02:21 pathway	Not fixed in calendar days by RTS	Class A–B: 3–6 months typical; Class C–D: 6–12 months typical	RTS 11.03.02:21; SRS practice
Devices — renewal window	6 months before expiry to 3 months after	5-year validity	Suspension + cancellation on lapse	RTS 11.03.02:21 §6.3.1.f
Devices — import expiry rule	Minimum 6 months to expiry required at import	Absolute rule (except special import)	Applies to every commercial import	RTS 11.03.02:21 §6.4.1.c
Clinical trials — CNEIS pleno review	Reviewers' written evaluations	4 to 6 weeks for pleno; 7 days for expedited	Followed by full pleno discussion session	Manual CNEIS
Clinical trials — SRS authorization	Post-CNEIS approval	Not fixed in calendar days	Substantial amendments require SRS resolution before implementation	RTS 11.03.02:21 §6.1.1.c
Clinical trials — investigational-product import	SRS authorization required	Not fixed	Requires prior CNEIS approval + current SRS trial authorization	RTS 11.03.02:21 §6.1.1.d
Establishment authorization	Director Técnico / Profesional Responsable / Referente de Tecnovigilancia inscription	Notification of absence > 15 days with 5 days' advance notice	1 month notice for Director Técnico resignation	RTS 11.03.02:21 §§6.2.4.1.i–j, 6.2.4.2.e–g

Sub-category	Procedure	Statutory timeline	Empirical / practical	Source
Used biomedical equipment	Maximum ordinary age from manufacture	5 years, extendable on SRS evaluation	Bilingual manuals mandatory	RTS 11.03.02:21 §6.4.3.d–e
Post-inspection remediation	Findings, recommendations, remediation deadlines	Set case-by-case in the inspection act	Duplicate signed act to Director Técnico	RTS 11.03.02:21 §§6.5.1.f–g
Apostille (Salvadoran documents outbound)	Ministerio de Relaciones Exteriores	Immediate upon issuance	Free of charge	RREE

The single most consequential timing rule for foreign sponsors is not stated in calendar days. RTS 11.03.02:21 is deliberately silent on review windows; the SRS operates on procedural queues, and completeness of the initial submission — including the correct apostille-then-translate sequencing — is the primary lever a sponsor controls.

Section H. Recent regulatory changes 2023–2026

2023 — Legislative Decree No. 891. *Ley de la Superintendencia de Regulación Sanitaria* approved by the Asamblea Legislativa in November 2023, establishing the SRS as the successor autonomous authority (SRS Ley; Asamblea Legislativa).

2023 (December) — Ley Especial de Precios (LEPS-DNM). Sets fees for DNM/SRS services, in force from 1 January 2024 with gradual implementation. Introduces exemptions for public institutions, orphan drugs, and patient-requested unavailable products (LEPS-DNM; SRS press).

2024 (June 19) — Legislative Decree No. 30, reform to Ley SRS. Amends the SRS creation law: shifts entry into force from 9 August 2024 to 7 August 2024; introduces Article 39-A granting a 120-business-day dissolution period for the DNM to ensure uninterrupted continuity of pending procedures; reduces the four planned intendencias to two — *Intendencia de Vigilancia* and *Intendencia de Registro e Inscripciones* (Diario Oficial No. 129, T. 444, 8 July 2024; LatinAlliance; Salud y Fármacos).

2024 (August 7) — SRS begins operations. SRS legally succeeds DNM and absorbs registration functions of MINSAL, MAG, and CSSP (Dinero SV; SRS).

2024 (September) — SRS budget approved. Asamblea Legislativa approves USD 7,269,060 budget for SRS covering August–December 2024 — a 48.2% reduction from DNM's prior USD 14.03M annual budget (Diario Co Latino; La Prensa Gráfica).

2025 (January 31) — First Superintendente appointed. MSc. Noé Geovanni García Iraheta (previously Director Nacional de Medicamentos) named as first *Superintendente de Regulación Sanitaria* (Portal de Transparencia).

2025 (March 24) — SRS Regulatory Agenda published. Includes commitments to publish 15 new regulations covering GCP, clinical-trial regulation, pharmacovigilance, cosmetovigilance, biological products, food registration, and post-registration modifications (SRS Agenda Regulatoria 2025).

2025 — Clinical Trials Law project. *Comisión de Salud* of the Asamblea Legislativa approves a project for a comprehensive *Ley de Ensayos Clínicos*, still pending plenary approval as of August 2026 (El Salvador — Comisión de Salud).

2025 (December 22) — Lineamientos Técnicos de Farmacovigilancia updated. Acuerdo Ejecutivo AE-3111 issued, updating spontaneous notification instruments and RAM classification procedures (Lineamientos FV).

2026 (April) — RTS 11.02.05:25 approved. Publication in *Diario Oficial* extends the RTS series covering pharmaceutical products (Jurisprudencia).

Section I. Amavita library cross-references

- Central American regulator overview: Global regulators post — paste-ready content
- Preclinical translation across 9 LATAM regulators (includes El Salvador section): Preclinical translation requirements — 9 LATAM regulators
- Sworn vs certified vs simple translation across LATAM: Sworn vs certified translation — regulatory submissions
- Spanish ICF readability standard: INFLESZ threshold — Spanish ICF readability
- RFI anatomy across LATAM regulators: RFI anatomy — six LATAM regulator rejections
- One-protocol-change amendment cascade: Amendment cascade — LATAM translation stack
- Three-band framework for LATAM translation: Three bands of LATAM regulatory translation
- Translation QC for regulatory dossiers: Translation QC — regulatory dossiers
- Costly translation mistakes across LATAM: Costly translation mistakes — regulatory submissions
- Platform vs traditional translation for LATAM regulators: Regulatory language infrastructure vs traditional translation

FAQ

Is the DNM still an active regulator, or has SRS fully replaced it?

Legally, the DNM was dissolved by Legislative Decree No. 891 and its reforms. Under Article 39-A of the reformed Ley SRS, a 120-business-day dissolution period was established to ensure pending files transitioned without interruption. As of August 2026, all new drug and device filings, renewals, and clinical-trial submissions go to the SRS. Existing DNM-issued sanitary registrations remain valid until their expiry; renewals are decided by the SRS (LatinAlliance; SRS Ley Arts. 39, 39-A, 40).

Do I need sworn translations of all my foreign technical documents?

No. El Salvador reserves traducción oficial (sworn translation) for legal-administrative instruments: Carta de Representación, apostilles, foreign CFS, foreign CPP, foreign GMP certificates, powers of attorney, and insurance certificates for clinical-trial participants. Technical documents (design reports, validation studies, clinical evaluation reports, risk-management reports) do not require sworn translation, though device labels and IFU/manuals for used biomedical equipment must be in castellano per RTS 11.03.02:21 §§6.3.4.d and 6.4.3.e (DNM Guide C02-RS-01-UR_PF.GUI01 v06 §5).

Can I file my primary-package labels with ISO 15223-1 symbology instead of Spanish text?

Yes, for medical devices. RTS 11.03.02:21 §6.3.4.d explicitly allows the primary-package label to be presented in castellano or via ISO 15223-1 symbology in its current version. This is one of the most permissive labelling rules in LATAM. Drugs, however, are governed by RTCA 11.01.02:04, which requires Spanish text on the label and insert.

Does El Salvador recognize foreign clinical trials?

Yes. RTS 11.03.02:21 §6.1.4(a) allows the SRS to recognize clinical trials authorized by high-surveillance agencies (FDA, EMA, PMDA, Health Canada, TGA) and by PAHO/WHO. The reliance clause also extends to decisions, requirements, reports, or information from agencies certified as PAHO/WHO level IV. This is a functional reliance clause, not automatic recognition — the SRS retains full discretion.

What are the CNEIS review timelines?

Full pleno review: reviewers file written evaluations electronically within 4 to 6 weeks. Expedited review (minimal-risk studies, minor amendments): 7 days. The pleno then discusses the study in the next scheduled session. After CNEIS approval, the SRS Unidad de Ensayos Clínicos issues the regulatory authorization (Manual CNEIS).

Can I reuse an El Salvador drug registration in other Central American countries?

Yes, through Reconocimiento Mutuo under RTCA 11.03.59:18 Anexo 2 (Resolution 446-2021 COMIECO-XCIV). A sanitary registration granted by any Central American member state's authority can be recognized by the others under harmonized criteria — reducing filing time in Guatemala, Honduras, Nicaragua, Costa Rica, and Panama. This is the single most important structural fact for sponsors planning multi-country Central American launches (SRS RTCA).

Is the apostille sequencing rule negotiable?

No. Foreign documents must be apostilled in the country of origin first, then translated in El Salvador by an authorized official translator. Translating first and apostilling the translation authenticates only the Salvadoran translation, not the underlying foreign document — and the SRS treats the underlying document as unauthenticated. Salvadoran documents outbound are apostilled by the Ministerio de Relaciones Exteriores free of charge and take immediate effect in Hague-Convention countries (RREE).

How does Amavita's 7th QC gate — Document Currency — apply in El Salvador?

El Salvador stacks two currency risks. First, the SRS transition (August 2024) means documents addressed to DNM after the dissolution period may face jurisdictional questions and require re-issuance to the successor unit. Second, the RTS regulations do not specify calendar-day review timelines, meaning a dossier can queue while its foreign documents age. Amavita's Document Currency gate timestamps every foreign document at three points — apostille issuance, translation delivery, filing to SRS — and re-issues a fresh translation within 48 hours if a sponsor refreshes an apostilled document under the First-Pass Acceptance Program ($2,500/business-day).

What clinical-trial framework changes are pending?

The SRS's 2025 regulatory agenda commits to a Guía de Buenas Prácticas Clínicas (AR-SRS-009) and a Regulación de ensayos clínicos (AR-SRS-012), with target adoption dates of June and July 2025 respectively. Separately, the Asamblea Legislativa's Comisión de Salud approved in 2025 a project for a comprehensive Ley de Ensayos Clínicos, still pending plenary vote (SRS Agenda 2025; Comisión de Salud).

Do I need a Salvadoran Apoderado Responsable and Profesional Responsable?

Yes. RTS 11.03.02:21 §§3.4, 3.13, 3.29, and 6.2.1.c–e require every sanitary-registration holder to designate: (a) an Apoderado Responsable — natural or legal person designated by power of attorney to respond before the regulator; (b) a Profesional Responsable — health-area professional authorized by CSSP and inscribed before SRS; and (c) a Director Técnico — health-area professional with device-specific competencies. All three must be inscribed before the SRS. Absences longer than 15 days must be notified with at least 5 days' advance notice.

About the author

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

Version history

This guide is version **1.4.0**, last updated August 25, 2026. Every substantive change to the SRS requirements on this page is recorded below.

v1.4.0 August 25, 2026

- Added a pending-state Regulator Consulta callout at the end of Section D. Consulta filed with the SRS Unidad de Ensayos Clínicos on 24 August 2026 (ensayos.clinicos@srs.gob.sv), courtesy follow-up 25 August 2026.
- Question on record: whether an English Investigator's Brochure with a Spanish summary satisfies SRS and CNEIS reviewers at CTA stage when the protocol is filed in full Spanish translation, under RTS 11.03.02:21 §§7.2–7.3 and the Manual CNEIS bifurcated-language rule.

v1.3.0 August 22, 2026

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

v1.2.0 August 22, 2026

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

v1.0.0 August 18, 2026

- Initial publication of the regulator translation requirements guide.