



## Argentina — IVD Renewal

Backend Gap Analysis vs. ANMAT Official Sources

 **HIGH GAP SCORE**

**In Vitro Diagnostics**

**Disposición 2198/2022**

**8/8**

Sub-tiles MISSING

**4**

HIGH Severity Gaps

**3**

MEDIUM Severity

**1**

LOW Severity

The RegDesk backend contains **no Argentina IVD Renewal tile content**. Official ANMAT sources (Disposición N° 2198/2022) provide a well-documented renewal framework. Immediate content creation is required across all sub-tiles.

**⚠ Critical Finding:** The RegDesk backend returned no Argentina IVD Renewal tile data. All findings below are sourced exclusively from official ANMAT publications. Late filing results in full registration cancellation — this risk must be prominently communicated in the Renewal tile.

| Sub-tile                  | Status  | Severity | Finding & Recommendation                                                                                                                                                                                                                                                                                                                          |
|---------------------------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Process Overview          | MISSING | HIGH     | No process overview in backend. Official source: 5-year validity, renewal before expiration via ANMAT digital platform, sworn declaration (declaración jurada), automatic extension if filed on time, cancellation if filed late. → <i>Create tile from Arts. 7–9, Disp. 2198/2022.</i>                                                           |
| Required Documents        | MISSING | HIGH     | No document list in backend. Annex IV Part A (Disp. 2198/2022) governs current registrations; Part B for pre-2022 registrations. Includes signed sworn declaration, current certificate, updated product data, updated labeling/IFU. → <i>Retrieve Annex IV PDF and populate sub-tile; differentiate Parts A and B.</i>                           |
| Timeline / Advance Notice | MISSING | HIGH     | No timeline information. ANMAT mandates filing before expiration — no minimum advance window specified by regulation, but late filing triggers automatic registration cancellation (full restart required). Industry best practice: file 6–12 months before expiry. → <i>Add timeline section with critical cancellation warning.</i>             |
| Legal Basis               | MISSING | HIGH     | No legal references. Primary: Disposición ANMAT N° 2198/2022, Boletín Oficial N° 34887 (25/03/2022). Background law: Ley N° 16.463; Decreto N° 1490/92. 2025 update: Disposición 8799/25 (low-risk IVD Groups A&B streamlining, effective March 2026 — affects habilitación, not renewal). → <i>Populate legal basis sub-tile with citations.</i> |
| Validity Period           | MISSING | MEDIUM   | No validity period in backend. Official source confirms 5 years per Art. 7, Disp. 2198/2022, renewable successively for equal 5-year periods. → <i>Add "5 years, renewable" citing Art. 7.</i>                                                                                                                                                    |
| Fees                      | MISSING | MEDIUM   | No fee information. Disp. 2198/2022 does not specify fees — ANMAT applies separate tariff schedules. Specific amounts not found in publicly reviewed sources. → <i>Note fee schedule reference; direct to ANMAT tramites portal; flag for INPM verification.</i>                                                                                  |
| Online Portal             | MISSING | MEDIUM   | No portal link. Art. 2, Disp. 2198/2022 mandates digital submission for all IVD procedures. Platform is the RPPTM system (Registro de Productores y Productos de Tecnología Médica), accessed via argentina.gob.ar/anmat/tramites. GDE/TAD platform also used. → <i>Add portal link; verify current platform name with INPM.</i>                  |
| Contact Information       | MISSING | LOW      | No contact info. ANMAT — Instituto Nacional de Productos Médicos (INPM): Av. de Mayo 869, C1084AAD, CABA. Tel: (54-11) 4340-0800. → <i>Add standard ANMAT/INPM contact block.</i>                                                                                                                                                                 |

Official Regulatory Framework — ANMAT (Disposición 2198/2022)

Primary source: **Disposición ANMAT N° 2198/2022** (DI-2022-2198-APN-ANMAT#MS), published in Boletín Oficial N° 34887 on 25/03/2022. Arts. 7–9 govern the IVD Renewal (Reválida) process. A 2025 update (Disposición 8799/25) streamlines habilitación for low-risk IVDs but does not alter the renewal process.

 **Renewal Process**

Registrant must file for *reválida* BEFORE the 5-year registration expires via ANMAT's digital platform (RPPTM system). Filed as a sworn declaration (declaración jurada). Timely filing automatically extends the current certificate during review. Late filing = full registration cancellation, requiring a new initial registration.

 **Required Documents**

Per Annex IV, Part A (post-2022 registrations): signed sworn declaration by Director Técnico + Responsable Legal; current registration certificate; updated product data; updated labeling/IFU (if applicable). Pre-2022 registrations use Part B — ANMAT to publish schedule. Full annex in Boletín Oficial PDF.

 **Validity & Timeline**

**Validity:** 5 years (Art. 7), renewable for successive 5-year periods.  
**Deadline:** Must file before expiration — no regulatory minimum advance window. Industry best practice: 6–12 months prior. Late filing = cancellation; no grace period.

 **Fees**

Not specified in Disposición 2198/2022. ANMAT applies separate tariff (arancel) schedules. Verify current amounts via the ANMAT tramites portal or contact INPM directly. Fees subject to periodic updates by Argentine government.

 **Online Portal**

Art. 2 mandates digital platform for all IVD procedures. System: RPPTM (Registro de Productores y Productos de Tecnología Médica). Access via: [argentina.gob.ar/anmat/tramites](http://argentina.gob.ar/anmat/tramites). Also uses GDE/TAD (Gestión Documental Electrónica / Trámites a Distancia) platform.

 **Legal Basis**

**Primary:** Disposición ANMAT N° 2198/2022, Arts. 7–9  
**Background:** Ley N° 16.463; Decreto N° 1490/92  
**Legacy:** Disposición 2674/99 (partially superseded)  
**2025 update:** Disposición 8799/25 (Groups A & B habilitación, eff. March 2026)

Sources Verified

1. Disposición ANMAT N° 2198/2022 — Full text | [argentina.gob.ar/normativa/nacional/norma-362696/texto](http://argentina.gob.ar/normativa/nacional/norma-362696/texto)
2. Boletín Oficial N° 34887 (25/03/2022) — Publication of Disposición 2198/2022 | [boletinoficial.gob.ar](http://boletinoficial.gob.ar)
3. ANMAT Official Portal | [argentina.gob.ar/anmat](http://argentina.gob.ar/anmat)
4. ANMAT Tramites Portal (RPPTM procedures) | [argentina.gob.ar/anmat/tramites](http://argentina.gob.ar/anmat/tramites)
5. Disposición 8799/2025 — Low-risk IVD streamlining (CureCompass coverage) | [curecompass.com.ar/nuevo-tramite/](http://curecompass.com.ar/nuevo-tramite/)