

French Polynesia — Regulatory Intelligence Gap Assessment

Regulator: Direction de la Santé de la Polynésie française (DSPF) / Ministère de la Santé
Country type: French overseas collectivity (collectivité d'outre-mer) — autonomous health legislation
Generated: July 9, 2026 | **Source:** Web research (lexpol.cloud.pf, DSPF, Tahiti Infos, Assemblée PF, CPS, EU TFEU)
WI reference: WI_551 RegDesk Backend System Work Instruction Version 4

Regulatory Framework — Key Findings

✓ Autonomous Territory — French Polynesia Has Its Own Health Laws

French Polynesia is a **collectivité d'outre-mer** governed under **Article 74 of the French Constitution**. Its autonomy statute is established by **Loi organique n° 2004-192 du 27 février 2004** (Statut d'autonomie de la Polynésie française).

- **ANSM does NOT apply** — ANSM is a French national agency; French Polynesia falls outside its territorial jurisdiction
- **EU MDR/MDD does NOT apply** — French Polynesia is an EU Overseas Country & Territory (OCT) under TFEU Annex II — NOT part of the EU single market
- **EU REACH does NOT apply** — same territorial limitation as EU MDR
- French Polynesia has **full competence ("compétence propre")** in health under its autonomy statute
- The **Assemblée de la Polynésie française** votes "Lois du Pays" (country laws) on health matters
- A local **Code de la santé de la Polynésie française** exists

✗ Regulatory Vacuum for Medical Devices

Despite the autonomous health framework, **no dedicated medical device law has been identified** in French Polynesia. The territory regulates pharmaceuticals (pharmacy monopoly, import restrictions) but medical devices appear to lack a dedicated pre-market authorization, classification, or vigilance framework. Most devices reach the market via importation from France (carrying CE marking as a de facto quality standard) without a separate local approval requirement.

Gap Assessment Summary

 — no registration, no classification system, no UDI, no formal vigilance



du Pays)



— CPS (Caisse de Prévoyance Sociale) manages local LPP (Liste des Produits et Prestations remboursables)



— CE-marked devices from France are the practical standard, but not legally required locally



Tile-by-Tile Gap Status — All Sections

#	Section / Tile	Gap Status	Backend Data Available?	Reference Law / Guidance
1	Regulatory Authority		No	Loi organique 2004-192; Local Code de la santé PF
2	Device Classification		No	None found — no local classification system
3	Market Authorization / Registration		No	None found — no pre-market registration requirement identified
4	QMS		No	None found — ISO 13485 not legally mandated locally
5	Clinical Trials		No	Loi Jardé (n° 2012-300) — unclear if extended to PF; French State CPP ethics
6	Importation		No	Customs (French State competency); local pharmacy import law (Loi du Pays)
7	UDI		No	None found — no local UDI system
8a	Labeling — Language		No	French official language (Constitution PF); de facto French labeling standard
8b	Labeling — Mandatory Elements		No	No specific MD labeling regulation found
8c	Labeling — Safety Symbols		No	No local symbols regulation; ISO 15223 used via CE-marked imports
8d	Labeling — Authorized Rep / PRRC		No	No local authorized representative requirement
8e	Labeling — Country of Origin		No	No specific requirement found
8f	Labeling — Size & Location		No	No specific requirement found
8g	Labeling — Unique Requirements		No	No unique local labeling requirements identified
9	CE Marking		No	EU MDR 2017/745 — NOT applicable (French Polynesia is EU OCT, not EU territory)
10	Advertisement & Promotion		No	No MD advertising regulation found; general consumer protection law applies
11	Packaging		No	No local sterile packaging regulation; ISO 11607 via CE imports (de facto)
12	Cybersecurity		No	No local cybersecurity requirement for medical devices
13	PMS (Post-Market Surveillance)		No	No local PMS system; no EUDAMED equivalent

#	Section / Title	Gap Status	Backend Data Available?	Reference Law / Guidance
14	Adverse Events / Vigilance	 GAP	No	No local MD vigilance reporting system; ANSM scope excludes French Polynesia
15	Recalls	 GAP	No	No formal local recall procedure; DSPF coordinates health alerts in practice
16	Renewals	 N/A	No	Not applicable — no registration system exists to renew
17	Timeline & Fees	 N/A	No	Not applicable — no pre-market registration; customs duties/taxes apply
18	e-Submission	 N/A	No	Not applicable — no submission portal for medical devices
19	Change Control	 N/A	No	Not applicable — no registration to notify changes to
20	OTC / Self-test Devices	 PARTIAL	No	Pharmacy monopole (Loi du Pays); distribution channels regulated (e.g. COVID tests)
21	Export Certificates (CFS)	 N/A	No	Not applicable — minimal local manufacturing; CFS from France/EU for imported devices
22	Transportation / Waste	 PARTIAL	No	Local environmental/health law; DSPF oversight of health facility waste; cold chain guidance
23	Battery / Shelf-Life	 GAP	No	No specific requirement found
24	REACH / RoHS / Chemical	 GAP	No	EU REACH (EC 1907/2006) — NOT applicable (OCT status); local environmental law unclear

Legend:  GAP = No regulation found / missing from backend |  PARTIAL = Some framework exists but incomplete | N/A = Not applicable (no registration system exists) |  = Data available

Detailed Findings by Section

1. Regulatory Authority PARTIAL

WI_551 Section: Common Regulations → Regulatory Authority

Finding: The **Direction de la Santé de la Polynésie française (DSPF)** is the primary health authority in French Polynesia. It operates under the **Ministère de la Santé** (local government). There is no dedicated medical device regulatory agency — health product oversight (drugs + devices) is managed through DSPF and pharmacy legislation. The **Ordre des pharmaciens de Polynésie française** is involved in pharmacy practice regulation.

Reference Laws / Guidances:

- Loi organique n° 2004-192 du 27 février 2004 portant statut d'autonomie de la Polynésie française
- Code de la santé de la Polynésie française (local health code)
- Article 74 of the French Constitution

Official Sources:

- <https://lexpol.cloud.pf> — Journal Officiel de la Polynésie française
- <https://hygiene-publique.gov.pf> — DSPF (direction de la santé)
- <https://gouvernement.pf> — Gouvernement de la Polynésie française

 **Note:** No dedicated medical device regulatory agency identified. Recommend contacting DSPF directly for confirmation of any device-specific oversight roles.

2. Device Classification ✖ GAP

WI_551 Section: Common Regulations → Device Classification

Finding: No specific local medical device classification system has been identified for French Polynesia. There is no ANSM authority and no EU MDR applicability, so there is no formal local classification system comparable to EU Class I/IIa/IIb/III or FDA Class I/II/III. CE marking is the de facto quality reference since most products come from France/EU, but no formal CE requirement has been confirmed for the local market.

Reference Laws / Guidances: None identified for French Polynesia

De facto reference: EU MDR 2017/745 classification rules (for CE-marked imports from France) — but NOT legally binding locally

Backend recommendation: Tag this section as "Not regulated" / regulatory gap. Note that CE-marked device classification from the country of origin is the practical standard.

3. Market Authorization / Registration ✖ GAP

WI_551 Section: Common Regulations → Market Authorization

Finding: No specific pre-market authorization or registration system for medical devices has been identified in French Polynesia. Unlike pharmaceuticals (which require authorization under local pharmacy laws and a pharmacy monopoly), medical devices do not appear to require a separate pre-market registration with a local authority before being placed on the market.

Reference Laws / Guidances: No specific Loi du Pays on medical device registration found. Pharmaceuticals: regulated under local drug law (pharmacy monopoly, Loi du Pays)

Sources searched:

- <https://lexpol.cloud.pf> — no medical device registration law identified
- Assemblée de la Polynésie française: <https://www.assemblee.pf> — no MD legislation found

Note: Medical devices sold commercially in French Polynesia are subject to general consumer protection law and customs clearance, but no dedicated pre-market device registration exists. The CPS reimbursement list (LPP) is the primary practical gate for devices.

4. QMS (Quality Management System) ✖ GAP

WI_551 Section: Common Regulations → QMS

Finding: No local requirement for ISO 13485 or any other QMS standard has been identified in French Polynesia. Since there is no local medical device regulatory framework, there is no formal QMS requirement imposed locally on manufacturers or importers. ISO 13485 may still be required by hospital purchasers or the CPS as a procurement condition, but this is not a regulatory mandate.

Reference Laws / Guidances: None identified
De facto: ISO 13485 expected on CE-marked imported devices; not a local legal requirement

5. Clinical Trials ⚠ PARTIAL

WI_551 Section: Common Regulations → Clinical Trials

Finding: Clinical trials involving human subjects in French Polynesia would involve a complex jurisdictional question. Research ethics (fundamental rights) may remain a French State competency, which would bring the **Comité de Protection des Personnes (CPP)** into scope. However, French Polynesia's autonomy

statute may give local competence over health research conducted in local facilities. No dedicated local clinical trial legislation for French Polynesia has been identified.

Reference Laws / Guidances:

- Loi Jardé n° 2012-300 (French national biomedical research law) — application to French Polynesia unclear
- French Polynesia autonomy statute — health as local competency
- WHO guidance applicable via WHO Western Pacific / Pacific Technical Support Division

Sources:

- WHO Western Pacific — French Polynesia: <https://www.who.int/westernpacific>

Note: Needs further investigation with DSPF. In practice, any clinical trial in French Polynesia would require coordination between local health authorities and French State bodies.

6. Importation PARTIAL

WI_551 Section: Common Regulations → Importation

Finding: Medical devices are subject to customs control (douane) at point of entry. Customs is a French State competency and applies uniformly. For **pharmaceuticals**, only licensed pharmacies and healthcare professionals may import; individuals may import medicines by prescription in limited quantities. For **medical devices specifically**, customs clearance applies but no specific import permit system for devices has been identified beyond general customs requirements.

Reference Laws / Guidances:

- French Polynesia customs code (local competency for tariffs; French State for border control)
- Local pharmacy import law (Loi du Pays — pharmacy monopole on drugs)
- Statement confirmed by customs officials, December 2024: *"Seuls les professionnels, comme les pharmacies, peuvent importer des médicaments, et sinon c'est sur ordonnance, en quantité très limitée."*

Sources:

- Tahiti Infos, Dec 2024: <https://www.tahiti-infos.com/lce-paka-LSD-Au-tri-postal...>
- <https://service-public.pf> — administrative procedures portal

Note: A 2024 Loi du Pays was proposed to facilitate importation of medicines for foreign athletes during the Paris 2024 Olympic surfing competition at Teahupo'o — demonstrating the territory can pass ad hoc import laws. Drug vs. device distinction in import rules needs confirmation from DSPF.

7. UDI (Unique Device Identification) GAP

WI_551 Section: Common Regulations → UDI

Finding: No local UDI system identified for French Polynesia. EU UDI (EUDAMED) does not apply. FDA UDI does not apply. No local UDI requirement has been found. EU UDI markings may appear on imported CE-marked devices as a factual matter, but this is not a local regulatory requirement.

Reference Laws / Guidances: None identified

8. Labeling (All Sub-sections) PARTIAL (language only)

WI_551 Section: Common Regulations → Labeling (7 sub-sections)

Finding: French is the official language of French Polynesia. French-language labeling is the practical expectation for all health products. No specific medical device labeling regulation has been identified locally (mandatory elements, font size, symbols, etc.). CE-marked devices imported from France typically carry French labeling per EU MDR/MDD requirements, providing a de facto standard.

8a. Language

Requirement: French (official language of French Polynesia)

Reference: French Polynesia Constitution (French = official language); de facto standard for all health products

Status:  **De facto — no formal MD labeling law**

8b–8g. Mandatory Elements / Symbols / Authorized Rep / Country of Origin / Size / Unique Requirements

Requirement: No specific local requirements found for any of these sub-sections

De facto: EU MDR labeling elements present on CE-marked imports (not legally required locally)

Status:  **GAP — no local MD labeling regulation**

 **Backend recommendation:** For all labeling sub-sections: tag "Not regulated locally" / "French language recommended". Note CE marking as the practical standard for imported devices.

9. CE Marking **GAP (not legally required)**

WI_551 Section: Common Regulations → CE Marking

Finding: CE marking is **not legally required** in French Polynesia under local law. EU MDR 2017/745 applies only in EU/EEA territory; French Polynesia is an OCT outside the EU single market. In practice, most medical devices used in local hospitals and clinics are imported from France and carry CE marking — making it the de facto quality standard — but it is not a local regulatory requirement.

Reference Laws / Guidances:

- EU MDR 2017/745 — NOT applicable (confirmed by TFEU Annex II — French Polynesia listed as EU OCT)
- EU MDD 93/42/EEC — NOT applicable (same reason)
- EU IVDR 2017/746 — NOT applicable (same reason)

Sources:

- TFEU Annex II — EU OCT list: confirms French Polynesia outside EU territory
- European Commission guidance on OCT status

10. Advertisement & Promotion **GAP**

WI_551 Section: Common Regulations → Advertisement

Finding: No specific medical device advertising regulation has been identified for French Polynesia. For pharmaceuticals, advertising is regulated under local pharmacy law. French national law on pharmaceutical advertising (Code de la santé publique, applicable in Metropolitan France) does not automatically extend to French Polynesia. General consumer protection law (droit de la consommation) in French Polynesia would apply to misleading advertising claims.

Reference Laws / Guidances:

- Local pharmacy/health law (Loi du Pays) — addresses pharmaceutical advertising, not specifically MD
- General consumer protection law — French Polynesia

11. Packaging **GAP**

WI_551 Section: Common Regulations → Packaging

Finding: No specific medical device packaging or sterility regulation identified for French Polynesia. CE-marked devices from the EU would already comply with EU standards (ISO 11607 for sterile packaging, etc.), providing a de facto standard for imported products.

Reference Laws / Guidances: None identified locally

De facto: ISO 11607 (sterile packaging) via EU MDR compliance of imported devices

12. Cybersecurity **GAP**

WI_551 Section: Common Regulations → Cybersecurity

Finding: No local cybersecurity requirement for medical devices identified in French Polynesia.

Reference Laws / Guidances: None identified

13. PMS (Post-Market Surveillance) ✗ GAP

WI_551 Section: Common Regulations → PMS

Finding: No specific post-market surveillance system for medical devices has been identified in French Polynesia. There is no local equivalent of EU EUDAMED or ANSM's vigilance system for devices. Serious adverse events would likely be handled through hospital reporting channels.

Reference Laws / Guidances: None identified

14. Adverse Events / Vigilance ✗ GAP

WI_551 Section: Common Regulations → Adverse Events

Finding: No specific medical device adverse event or vigilance reporting system identified for French Polynesia. ANSM handles pharmacovigilance for Metropolitan France and overseas departments (DOM), but **NOT for French Polynesia** (which is a collectivité d'outre-mer with its own health competence). In practice, ANSM safety alerts are communicated to the local Ordre des pharmaciens as information (not as regulatory mandate) — as evidenced by the October 2023 vasoconstricteur warning.

Reference Laws / Guidances:

- ANSM: territorial scope confirmed as French national territory only — French Polynesia excluded
- DSPF handles local health incident coordination (in practice)

Sources:

- ANSM website — périmètre d'action: <https://ansm.sante.fr>
- Tahiti Infos — ANSM vasoconstricteur alert communicated to local pharmacy order (Oct 2023)

15. Recalls ✗ GAP

WI_551 Section: Common Regulations → Recalls

Finding: No specific medical device recall procedure identified under French Polynesia local law. In practice, French/EU recalls of medical devices would be communicated through supply chain channels and local distributors/importers would act accordingly. The DSPF (local health ministry) would coordinate health alerts.

Reference Laws / Guidances: None identified locally

Practical: EU/France recall communications flow through supply chain to local importers

16. Renewals N/A

WI_551 Section: Common Regulations → Renewals

Finding: Not applicable. No registration system for medical devices exists in French Polynesia, therefore there are no renewal requirements or renewal timelines.

17. Timeline & Fees N/A

WI_551 Section: Common Regulations → Timeline & Fees

Finding: Not applicable as a regulatory matter. No pre-market registration system exists. Customs duties and taxes apply to imported devices per French Polynesia's customs/tax code (local competency).

Reference: French Polynesia customs code (for import duties — not a device registration fee)

18. e-Submission N/A

WI_551 Section: Common Regulations → e-Submission

Finding: Not applicable. No electronic submission portal for medical devices exists in French Polynesia.

19. Change Control N/A

WI_551 Section: Common Regulations → Change Control

Finding: Not applicable. No registration system exists, therefore no change notification requirements.

20. OTC / Self-test Devices ⚠ PARTIAL

WI_551 Section: Common Regulations → OTC

Finding: No specific OTC/self-test medical device regulation has been identified, but the pharmacy monopole creates a *de facto* distribution restriction for certain health products. During COVID-19, rapid antigen test kits were distributed through pharmacies under health authority guidance — demonstrating that local authorities can and do regulate distribution channels for diagnostic devices through pharmacy law even without specific device legislation.

Reference Laws / Guidances:

- Local pharmacy law (Loi du Pays — pharmacy monopole provisions)
- Health authority COVID-19 guidance on test kit distribution (2020–2023)

21. Export Certificates (CFS) N/A

WI_551 Section: Common Regulations → Export Certificates

Finding: Not applicable from a local French Polynesia perspective. French Polynesia has very limited local medical device manufacturing. Any Certificate of Free Sale for devices sold in French Polynesia would originate from France or another EU country (the manufacturer's country). French Polynesia does not issue CFS for devices.

22. Transportation / Medical Waste ⚠ PARTIAL

WI_551 Section: Common Regulations → Transportation / Waste

Finding: Medical waste management is regulated under local environmental and health law, overseen by the DSPF. Cold chain requirements for temperature-sensitive health products (vaccines, biologics) exist and are enforced through local health authority guidelines. The dispersed island geography of French Polynesia (121 islands) makes cold chain management a significant practical concern for medical product distribution.

Reference Laws / Guidances:

- Local environmental and public health law (Polynésie française)
- DSPF oversight of health facility waste management
- WHO Western Pacific cold chain guidelines (applicable reference)

23. Battery / Shelf-Life ✗ GAP

WI_551 Section: Common Regulations → Battery / Shelf-Life

Finding: No specific requirements found for battery disposal or shelf-life regulation for medical devices in French Polynesia.

Reference Laws / Guidances: None identified

24. REACH / RoHS / Chemical Restrictions ✗ GAP

WI_551 Section: Common Regulations → Chemical Restrictions

Finding: EU REACH (Regulation EC 1907/2006) does NOT apply to French Polynesia — confirmed by its OCT status under the TFEU. No REACH-equivalent local legislation has been identified for French Polynesia. EU RoHS also does not apply. French Polynesia has its own environmental regulations, but no chemical restriction regime equivalent to REACH/RoHS for medical devices has been found.

Reference Laws / Guidances:

- EU REACH (EC 1907/2006) — explicitly NOT applicable (French Polynesia is EU OCT)
- EU RoHS Directive 2011/65/EU — NOT applicable (same reason)
- TFEU Annex II — confirms French Polynesia OCT status

CPS Reimbursement — Practical Regulatory Lever

CPS LPP — Liste des Produits et Prestations remboursables ✓ EXISTS

Finding: The **Caisse de Prévoyance Sociale (CPS)** manages health insurance reimbursements in French Polynesia, including a local **LPP (Liste des Produits et Prestations remboursables)** for medical devices and health products. This reimbursement listing is the primary practical gate for devices in the local market — products not on the LPP are not reimbursable and therefore have limited market uptake.

Significance: While not a regulatory authorization, CPS listing is the key commercial/access requirement for medical devices in French Polynesia. Manufacturers seeking market access should target CPS LPP listing as the primary pathway.

Source: <https://www.cps.pf> — Caisse de Prévoyance Sociale de la Polynésie française

Reference Laws & Guidances — Complete List

Reference	Type	Relevance to Medical Devices	Applicable?
Loi organique n° 2004-192 du 27 février 2004 portant statut d'autonomie de la Polynésie française	Constitutional / Autonomy Statute	Establishes French Polynesia's competence over health, including health products	✓ Yes — foundational law
Article 74 of the French Constitution	French Constitutional Law	Legal basis for French Polynesia's autonomous status	✓ Yes — constitutional basis
Code de la santé de la Polynésie française	Local Health Code	Covers pharmaceuticals, pharmacy monopoly; medical devices coverage unclear	✓ Applies (extent for MD unknown)
Lois du Pays — Assemblée de la Polynésie française	Local Legislation	Country laws covering health, pharmacy, importation. No MD-specific law found.	✓ Applies (no MD-specific law found)

Reference	Type	Relevance to Medical Devices	Applicable?
EU MDR — Regulation (EU) 2017/745	EU Regulation	Medical device regulation	✗ NOT applicable — French Polynesia is EU OCT (TFEU Annex II)
EU MDD — Directive 93/42/EEC	EU Directive	Former medical device directive	✗ NOT applicable — same reason
EU IVDR — Regulation (EU) 2017/746	EU Regulation	In vitro diagnostic devices	✗ NOT applicable — same reason
EU REACH — Regulation (EC) 1907/2006	EU Regulation	Chemical substances in products	✗ NOT applicable — same reason
EU RoHS — Directive 2011/65/EU	EU Directive	Hazardous substances in electrical equipment	✗ NOT applicable — same reason
Loi Jardé — n° 2012-300	French National Law	Biomedical research / clinical trials	⚠ Unclear — French national law; extension to PF uncertain
TFEU Annex II — EU OCT List	EU Treaty	Confirms French Polynesia's OCT status (outside EU single market)	✓ Applicable — confirms EU law exclusion
CPS — Liste des Produits et Prestations (LPP)	Reimbursement List	Medical device reimbursement — key market access requirement	✓ Applicable — primary practical gate
WHO Western Pacific Technical Support guidance	International Guidance	Applicable health guidance for Pacific island territories	✓ Reference only — non-binding

Official Sources & Regulatory Websites

Authority / Source	URL	Notes
Direction de la Santé de la Polynésie française (DSPF)	https://hygiene-publique.gov.pf	Primary health authority — key contact for MD queries
Gouvernement de la Polynésie française	https://gouvernement.pf	Ministère de la Santé; official government portal
Journal Officiel de la Polynésie française	https://lexpol.cloud.pf	Primary legal database — all Lois du Pays, arrêtés, regulations
Assemblée de la Polynésie française	https://www.assemblee.pf	Legislative texts and Lois du Pays
Caisse de Prévoyance Sociale (CPS)	https://www.cps.pf	Health insurance; LPP reimbursement list for devices
Service-Public Polynésie française	https://service-public.pf	Administrative procedures portal
ANSM (France — national agency)	https://ansm.sante.fr	⚠ NOT the regulatory authority for French Polynesia; alerts communicated informally
WHO Western Pacific / Pacific Technical Support	https://www.who.int/westernpacific	International guidance for Pacific island territories

Recommendations for RegDesk Backend Population

Action	Priority	Details
Tag all MD tiles as "Not regulated / Regulatory gap"	High	No dedicated MD law found. Use standard WI_551 language for unregulated sections.
Populate Regulatory Authority tile	High	DSPF / Ministère de la Santé PF. Reference Loi organique 2004-192.
Add framework explanation to Country Overview	High	Explain OCT status: not EU, not ANSM. Autonomous health competence. De facto CE standard from France.
Populate Labeling — Language	Medium	French required (official language). Reference local Constitution / language law.
Populate Importation tile	Medium	Customs (French State), no specific MD import permit found. Pharmacies for drug imports.
Add CPS LPP note to Market Authorization	Medium	CPS listing is the key practical market access gate even without formal registration.
Add note on CE de facto standard	Medium	CE marking not legally required but de facto standard for all imported devices from France/EU.
Direct confirmation from DSPF	High	Recommend direct outreach to DSPF to confirm absence of MD-specific regulation and any pending Lois du Pays.
Search full Code de la santé PF	High	Full text inaccessible during research. Manual search of lexpol.cloud.pf via JavaScript browser needed.

Research Limitations

- **DSPF website (hygiene-publique.gov.pf)** was inaccessible during research — DNS failed. Direct outreach recommended.
- **lexpol.cloud.pf** requires JavaScript for full-text search — full Code de la santé PF text not retrieved. Manual browser search needed.
- **CPS LPP device list** not retrieved — cps.pf portal accessed but full LPP list requires authentication.
- No French Polynesia-specific peer-reviewed regulatory literature found — this is an understudied territory.
- **Confidence level:** Framework findings (OCT status, ANSM exclusion, no EU MDR) — HIGH. Absence of specific MD law — MEDIUM (could exist in Code de la santé PF, not confirmed either way).