

French Polynesia — Medical Device Regulatory Gap Assessment

Prepared by: RegDesk Regulatory Intelligence Unit | Date: July 8, 2026 | Version: 1.0

Regulatory Authority: Direction de la Santé de Polynésie française (DSP) — <https://www.service-public.pf/dsp/>



Executive Summary

French Polynesia is a **French Overseas Collectivity (Collectivité d'outre-mer)** under Article 74 of the French Constitution. It has broad autonomous self-governance since its **2004 Statute of Autonomy**. French Polynesia enacts its own laws ("*Lois du pays*") via its *Assemblée de la Polynésie française*.



CRITICAL: The EU Medical Device Regulation (EU 2017/745) does **NOT** apply. The French national *Code de la Santé Publique* does **NOT** automatically apply. French Polynesia enacts its own laws via its own legislature.

OVERALL FINDING: No dedicated medical device regulatory framework has been identified in French Polynesia. Medical devices are imported and used without pre-market authorization requirements. Regulatory coverage is largely absent across all standard tiles.



Summary Statistics

Status	Count
✗ Full Gap	17
⚠ Partial Coverage	4
ℹ Not Applicable	3
TOTAL	24



Legislation Module

#	Law Title	Type	Year	Status	Reference
1	Loi organique n° 2004-192 du 27 février 2004 portant statut d'autonomie de la Polynésie française	Organic Law	2004	Active	legifrance.gouv.fr

#	Law Title	Type	Year	Status	Reference
2	Loi du pays n° 2026-4 du 15 mai 2026 — Code des douanes de Polynésie française	Customs Law	2026	Active	assemblee.pf
3	Arrêté n° 1771 CM du 26 août 2021 portant organisation de la Direction de la Santé	Ministerial Decree	2021	Active	lexpol.cloud.pf
4	Loi du pays n° 2017-25 du 27 juillet 2017 relative à la prévention et à la gestion des déchets en Polynésie française	Environmental Law	2017	Active	lexpol.cloud.pf
5	Arrêté n° 3149 CM du 20 novembre 2019 fixant les modalités de gestion de certaines catégories de déchets	Implementing Decree	2019	Active	lexpol.cloud.pf
6	EU MDR (EU) 2017/745	EU Regulation	2017	NOT APPLICABLE	—
7	EU IVDR (EU) 2017/746	EU Regulation	2017	NOT APPLICABLE	—

Tile-by-Tile Assessment (24 Tiles)

Tile 1 — QMS (Quality Management System) Full Gap

Status	 Full Gap
Gap Level	Full Gap
Reference Laws	None identified
Finding	No QMS requirements for medical device manufacturers or importers. DSP's internal <i>Cellule biomédicale</i> (Arrêté n° 1771 CM, 2021) manages hospital equipment maintenance only — not a manufacturer QMS requirement.
Recommendation	Flag as regulatory gap. Note international ISO 13485 best practice.

Tile 2 — Clinical Trials Full Gap

Status	 Full Gap
Gap Level	Full Gap
Reference Laws	None identified
Finding	No specific law governing medical device clinical trials. DSP conducts epidemiological surveillance but no clinical trial framework for medical devices exists. It is unclear whether the French national Jardé Law (n° 2012-300) applies by administrative practice.
Recommendation	Flag as gap. Seek clarification from DSP on Jardé Law applicability.

Tile 3 — Importation Partial Coverage

Status	 Partial Coverage
Gap Level	Partial
Reference Laws	Loi du pays n° 2026-4 du 15 mai 2026 — Code des douanes de Polynésie française (assemblee.pf)

Finding	A Customs Code was enacted in 2026. Medical devices pass through standard customs (general goods import). No dedicated pre-market authorization, registration, or import permit system for medical devices exists. DSP's <i>Pharmacie d'approvisionnement</i> handles internal DSP facility supply only — not a market authorization mechanism.
Recommendation	Document customs process as partial coverage. Flag medical device authorization requirement as a regulatory gap.

✗ Tile 4 — UDI (Unique Device Identification) Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None. EU EUDAMED/UDI system does not apply.
Finding	No UDI system implemented. No local UDI database, no AIDC/HIBC/GS1 requirement.
Recommendation	Full gap.

✗ Tile 5a — Labeling — General Requirements Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None identified
Finding	No specific general labeling requirements for medical devices identified.
Recommendation	Full gap.

⚠ Tile 5b — Labeling — Language Partial Coverage

Status	⚠ Partial Coverage
Gap Level	Partial
Reference Laws	None specific to medical devices. French is the official language per constitutional framework.
Finding	French is the official language of French Polynesia. No law explicitly mandates French-language labels for medical devices. French-language labels are consistent with practice but no formal mandate confirmed.
Recommendation	Note French as de facto official language. Flag explicit mandate as a gap; recommend authority contact.

✗ Tile 5c — Labeling — Primary Packaging Label Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No specific requirements for primary packaging labeling of medical devices.

Reference Laws	None. EU MDR symbol requirements (ISO 15223-1) do not apply.
Finding	No mandatory standardized symbol requirements for medical device labels.
Recommendation	Full gap.



Tile 6 — CE Marking

Not Applicable

Status	Not Applicable
Gap Level	N/A
Reference Laws	EU 2017/745 — NOT applicable. EU 2017/746 — NOT applicable.
Finding	French Polynesia is NOT part of the EU or EEA. CE marking is neither required nor sufficient for legal market access in French Polynesia. No local conformity marking scheme has been enacted.
Recommendation	Document as not applicable. Flag absence of any local conformity marking requirement as a regulatory gap.



Tile 7 — Advertisement & Promotion

Full Gap

Status	Full Gap
Gap Level	Full Gap
Reference Laws	None specific to medical devices
Finding	No sector-specific regulation for medical device advertising or promotion identified. General consumer protection principles may apply.
Recommendation	Full gap.



Tile 8 — Packaging

Full Gap

Status	Full Gap
Gap Level	Full Gap
Reference Laws	None specific to medical devices
Finding	No medical device-specific packaging requirements (materials, sterile barrier, design) found.
Recommendation	Full gap.



Tile 9 — Cybersecurity

Full Gap

Status	Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No cybersecurity requirements for connected or software-based medical devices.
Recommendation	Full gap.

✗ Tile 10 — Post Market Surveillance (PMS) Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	Arrêté n° 1771 CM du 26 août 2021 — covers disease surveillance only, not device PMS.
Finding	DSP's <i>Bureau de Veille Sanitaire</i> monitors public health/infectious diseases under International Health Regulations. No medical device PMS system, PSUR requirement, or PMCF framework identified.
Recommendation	Full gap for device-specific PMS.

⚠ Tile 11 — Adverse Event Reporting Partial Coverage

Status	⚠ Partial Coverage
Gap Level	Partial
Reference Laws	Arrêté n° 1771 CM du 26 août 2021 portant organisation de la Direction de la Santé (Bureau de Veille Sanitaire) Contact: veille.sanitaire@administration.gov.pf / (+689) 40.48.82.01
Finding	DSP has a general undesirable event (<i>'événement indésirable'</i>) reporting system and mandatory disease notification (<i>maladies à déclaration obligatoire</i>). These cover infectious diseases and food-related incidents — NOT medical device adverse events. No device vigilance database, no mandatory device-incident reporting mechanism.
Recommendation	Partial coverage for general health adverse events. Full gap for device-specific vigilance.

✗ Tile 12 — Recalls Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None identified
Finding	No medical device recall regulation, mandatory procedure, or authority mandate. No equivalent of FDA MedWatch, ANSM recall framework, or any recall database.
Recommendation	Full gap.

i Tile 13 — Renewals Not Applicable

Status	i Not Applicable
Gap Level	N/A
Reference Laws	None
Finding	No device registration system exists in French Polynesia; therefore no renewal requirements apply.
Recommendation	Not applicable — predicated on a registration system that does not exist.

✗ Tile 14 — Timeline & Fees Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No established service fees or regulatory timelines for medical device authorization, as no authorization system exists.
Recommendation	Full gap.

✗ Tile 15 — e-Submission Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No electronic submission portal for medical devices. DSP has a general health professional portal (service-public.pf/dsp/) but no device-specific e-submission tool.
Recommendation	Full gap.

✗ Tile 16 — Battery Requirements Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No battery safety, compliance, or disposal requirements specific to medical devices.
Recommendation	Full gap.

✗ Tile 17 — Shelf-Life Requirements Full Gap

Status	✗ Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No shelf-life validation or stability requirements for medical devices found.
Recommendation	Full gap.

Tile 18 — REACH Not Applicable / No Local Equivalent

Status	 Not Applicable / ✗ No Local Equivalent
Gap Level	N/A (EU scope) / Full Gap (local)
Reference Laws	EU REACH (EC 1907/2006) — NOT applicable.

Finding	EU REACH does not apply. No local chemical substances legislation equivalent to REACH for medical devices identified.
Recommendation	Document EU REACH non-applicability. Flag absence of local chemical substance controls as a gap.



Tile 19 — RoHS

Not Applicable / No Local Equivalent

Status	Not Applicable / No Local Equivalent
Gap Level	N/A (EU scope) / Full Gap (local)
Reference Laws	EU RoHS (2011/65/EU) — NOT applicable.
Finding	EU RoHS does not apply. No local restriction on hazardous substances in electrical/electronic medical device equipment found.
Recommendation	Full gap locally.



Tile 20 — Change Control

Full Gap

Status	Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No requirement to notify the authority of design, material, software, or manufacturing changes to marketed devices.
Recommendation	Full gap.



Tile 21 — OTC Requirements

Full Gap

Status	Full Gap
Gap Level	Full Gap
Reference Laws	None specific to OTC medical devices
Finding	No OTC-specific medical device rules. General retail/consumer law may apply but no device-specific OTC framework found.
Recommendation	Full gap.



Tile 22 — Export Certificates

Full Gap

Status	Full Gap
Gap Level	Full Gap
Reference Laws	None
Finding	No formal procedure identified for DSP or any authority to issue export certificates (CFS, CFG, Health Certificate) for medical devices.
Recommendation	Full gap.

✖ Tile 23 — Transportation & Storage Full Gap

Status	✖ Full Gap
Gap Level	Full Gap
Reference Laws	None specific to medical devices
Finding	No transport or storage requirements specific to medical devices identified. General goods transport rules may apply.
Recommendation	Full gap.

⚠ Tile 24 — Waste Management Partial Coverage

Status	⚠ Partial Coverage
Gap Level	Partial
Reference Laws	• Loi du pays n° 2017-25 du 27 juillet 2017 relative à la prévention et à la gestion des déchets en Polynésie française (lexpol.cloud.pf) • Arrêté n° 3149 CM du 20 novembre 2019 fixant les modalités de gestion de certaines catégories de déchets (lexpol.cloud.pf)
Finding	French Polynesia has a general waste management law (2017) covering hazardous waste (<i>déchets dangereux</i>). Medical waste (<i>déchets d'activités de soins — DASRI</i>) is likely covered under the general hazardous waste framework, but no device-specific WEEE/e-waste or end-of-life medical device regulation was identified.
Recommendation	Partial through general waste law. Research DASRI-specific provisions further. Recommend direct DSP inquiry.

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