

French Polynesia — Medical Device Regulatory Gap Assessment

RegDesk Regulatory Intelligence | Authority: DSPF (Direction de la Santé de la Polynésie française) | Generated: July 9, 2026

Scope: All WI_551 tiles · Based on RegDesk Backend Work Instruction framework · Reference laws included

French Polynesia — Regulatory Overview

Regulatory Authority: Direction de la Santé de la Polynésie française (DSPF)

Jurisdiction Type: French Overseas Collectivity (Collectivité d'outre-mer) — Article 74 of French Constitution

Autonomy Statute: Loi organique n°2004-192 du 27 février 2004

Primary Legal Source: Journal Officiel de la Polynésie française (JOPF) — [lexpol.cloud.pf](#)

ANSM Jurisdiction: ❌ ANSM (France) does NOT have regulatory jurisdiction over French Polynesia

EU MDR Applicability: ❌ EU MDR 2017/745 does NOT directly apply — CE marking under EU Directives (93/42/EEC, 90/385/EEC, 98/79/EC) is the de facto recognized standard

Official Language: French (Tahitian also recognized)

⚠️ Key Context: French Polynesia exercises full autonomy over health regulation. Its medical device framework is less developed than mainland France — CE-marked devices (under EU Directives) are the primary accepted standard, and most detailed device-specific regulation (UDI, cybersecurity, e-submission, REACH/RoHS) has not been enacted locally. The main law governing medical devices is **Délibération n° 2000-153 APF du 6 décembre 2000**, supplemented by the **Code de la Santé de la Polynésie française**.

Gap Assessment Summary

5	9	8	22
✔️ Regulated	⚠️ Partially Regulated	❌ Not Regulated / Gap	Total Tiles Assessed

#	Tile / Section	Status	Key Reference	Backend Content
1	Device Classification	⚠️ Partial	Délibération n°2000-153 APF; EU Directives (by reference)	❌ Not in backend
2	Market Authorization / Registration	⚠️ Partial	Délibération n°2000-153 APF; Code de la Santé PF	❌ Not in backend
3	QMS	❌ Gap	No specific QMS regulation	❌ Not in backend
4	Clinical Trials	⚠️ Partial	Code de la Santé PF (recherches biomédicales); CEPF Ethics Committee	❌ Not in backend
5	Importation	✔️ Regulated	Arrêté n°635 CM du 26/05/2006; Délibération n°2000-153 APF	❌ Not in backend
6	UDI	❌ Gap	No regulation identified	❌ Not in backend
7	Labeling	⚠️ Partial	Délibération n°2000-153 APF; Consumer protection laws PF	❌ Not in backend
8	CE Marking	✔️ Regulated	Délibération n°2000-153 APF; EU Directives 93/42, 90/385, 98/79 (recognized)	❌ Not in backend

#	Title / Section	Status	Key Reference	Backend Content
9	Advertisement & Promotion	⚠️ Partial	Code de la Santé PF (publicité produits de santé)	❌ Not in backend
10	Packaging	⚠️ Partial	Délibération n°2000-153 APF; CE framework (EN ISO 11607)	❌ Not in backend
11	Cybersecurity	❌ Gap	No device-specific regulation	❌ Not in backend
12	PMS	⚠️ Partial	Code de la Santé PF (vigilance sanitaire); Délibération n°2000-153 APF	❌ Not in backend
13	Adverse Events / Vigilance	✅ Regulated	Code de la Santé PF (matériorvigilance)	❌ Not in backend
14	Recalls	✅ Regulated	Code de la Santé PF; Délibération n°2000-153 APF	❌ Not in backend
15	Renewals	❌ Gap	No formal renewal system (no registration system)	❌ Not in backend
16	Timeline & Fees	❌ Gap	Not publicly documented	❌ Not in backend
17	e-Submission	❌ Gap	No portal — paper/email only	❌ Not in backend
18	REACH / RoHS	N/A	EU-specific — does not apply in PF	❌ Not in backend
19	OTC / Self-Test Devices	⚠️ Partial	Code de la Santé PF (DMDIV); ad hoc COVID arrêtés 2021-2022	❌ Not in backend
20	Export Certificates	⚠️ Partial	DSPF (ad hoc — no formal regulation)	❌ Not in backend
21	Transportation & Waste	⚠️ Partial	DASRI arrêté (medical waste); general environmental law PF	❌ Not in backend
22	Change Control	❌ Gap	No regulation identified	❌ Not in backend

📋 **Backend Status:** French Polynesia has **zero content** in the RegDesk backend across all tiles. This is a complete greenfield population task.

Detailed Tile Assessments

1. Device Classification ⚠️ Partial

Regulatory Framework

French Polynesia has not enacted a standalone device classification law. The classification framework is derived from the French Code de la Santé Publique (CSP) adapted locally through the **Code de la Santé de la Polynésie française** and **Délibération n° 2000-153 APF du 6 décembre 2000**, which references European Directive 93/42/CEE classification rules.

Classification System

- **Medical Devices:** Classes I, IIa, IIb, III — based on EU Directive 93/42/EEC Annex IX classification rules (intended purpose, duration of contact, invasiveness, active/non-active, implantability)

- **Active Implantable Devices:** Governed separately per principles of EU Directive 90/385/EEC
- **In Vitro Diagnostic Devices:** List A (highest risk), List B, self-test IVDs, general IVDs — per EU Directive 98/79/EC framework
- **Note:** EU MDR 2017/745 classification (Rule 1–22) does NOT apply — EU Directives are the referenced standard

References:

- Délibération n° 2000-153 APF du 6 décembre 2000 — portant réglementation des dispositifs médicaux en Polynésie française
- Code de la Santé de la Polynésie française (Titre V — Dispositifs médicaux)
- EU Directive 93/42/CEE (Annex IX) — referenced classification rules
- EU Directive 90/385/CEE — active implantable devices
- EU Directive 98/79/CE — in vitro diagnostics
- Source: lexpol.cloud.pf

Gap Assessment

Classification criteria exist in principle (through EU Directive reference) but are not fully codified in a standalone, publicly available Polynesian regulatory instrument. No classification guidance document has been published by DSPF. Backend requires: definition, classification rules, risk classes, and reference laws.

2. Market Authorization / Registration Partial

Regulatory Framework

French Polynesia does **not** operate a comprehensive pre-market authorization or registration system. There is no Polynesian device registry equivalent to EUDAMED. Market access is primarily facilitated through:

1. **CE Marking recognition** — devices with valid CE marking under EU Directives (93/42, 90/385, 98/79) are accepted for importation and distribution
2. **Prior DSPF Authorization** — mandatory for Class III devices and Active Implantable Devices (AIDs) before placing on market
3. **Importer Licensing** — the Polynesian importer must hold a DSPF-issued authorization

Key Requirements

- Class I / IIa: CE marking + licensed importer — no pre-market submission to DSPF required
- Class IIb / III: CE marking required; Class III additionally requires DSPF prior authorization
- Active Implantable Devices: Separate prior authorization from DSPF required
- Non-CE-marked devices: Technical dossier demonstrating equivalence required for DSPF review
- No national device database or registration number issued

References:

- Délibération n° 2000-153 APF du 6 décembre 2000
- Code de la Santé de la Polynésie française (Titre V)
- Loi du Pays n° 2014-12 LP du 6 mars 2014 relative à la politique de santé
- Source: lexpol.cloud.pf

Gap Assessment

Regulatory framework exists but lacks published procedural guidance. No online portal, no standard dossier template, no published timelines or fees. Content available for: definition, criteria (CE marking + prior auth for Class III), general principles. Procedure steps, documents, and fees sections have significant gaps due to lack of DSPF-published guidance.

3. Quality Management System (QMS) Gap

Regulatory Framework

No explicit QMS requirement has been enacted in French Polynesia. There is no local mandate for ISO 13485 certification for manufacturers marketing devices in French Polynesia. The territory relies on CE marking conformity assessment (which implicitly includes QMS audit for Class IIa and above) as a proxy.

Key Findings

- No ISO 13485 requirement in Polynesian law
- No GMP inspection framework for medical device manufacturers
- MDSAP: Not applicable — French Polynesia is not an MDSAP-recognized market
- Manufacturers established in French Polynesia (very rare): must comply with general health product manufacturing provisions in the Code de la Santé PF, but no device-specific QMS standard is codified
- CE marking conformity assessment (Notified Body involvement for Class IIa+) serves as de facto QMS recognition

References:

- Code de la Santé de la Polynésie française (general health product manufacturing provisions)
- MDSAP: Not applicable
- ISO 13485: Not mandated locally
- Source: lexpol.cloud.pf

Gap Assessment

Complete gap for standalone QMS content. Backend entry for this tile would use the standard "not regulated" statement: *"At present, no official source or documentation confirms a standalone QMS regulatory framework specific to medical devices in French Polynesia. Manufacturers are expected to maintain conformity with the CE marking requirements applicable to their device class."*

4. Clinical Trials Partial

Regulatory Framework

Clinical research in French Polynesia is regulated under the Code de la Santé de la Polynésie française's provisions on *recherches biomédicales*, adapted from the French Loi Huriet-Sérusclat (1988) and Loi Jardé (2012) principles. No device-specific clinical investigation regulation analogous to EU MDR Annex XV exists locally.

Key Requirements

- **Ethics Committee:** Approval required from the **Comité d'Éthique de la Polynésie française (CEPF)** — local IRB
- **Sponsor Notification:** Sponsors must notify DSPF before initiating a clinical investigation
- **Informed Consent:** Mandatory — per general biomedical research rules
- **Adverse Event Reporting during trial:** Required to DSPF and CEPF
- **Protocol Registration:** No local clinical trial registry — international registries acceptable
- No specific device clinical investigation dossier requirements published by DSPF
- PMCF, CER, PMPF: Not specifically regulated locally

References:

- Code de la Santé de la Polynésie française (Titre on recherches biomédicales)
- Comité d'Éthique de la Polynésie française (CEPF) — ethics committee regulations
- Loi du Pays n° 2014-12 LP du 6 mars 2014
- Source: lexpol.cloud.pf; CEPF

Gap Assessment

General biomedical research framework exists; device-specific clinical investigation guidance is absent. Backend can be populated with general principles (ethics approval, DSPF notification, informed consent), noting that device-specific procedure requirements are not codified.

5. Importation

Regulatory Framework

Importation is the most substantively regulated area for medical devices in French Polynesia. Requirements are established under the Code de la Santé de la Polynésie française and associated executive orders.

Key Requirements

- **Importer Authorization:** Importers of medical devices must hold a valid authorization (agrément) issued by DSPF — Pharmacie et Médicaments division
- **CE Marking:** All imported devices must bear valid CE marking under applicable EU Directive (93/42, 90/385, or 98/79) — this is the primary quality/conformity criterion for customs clearance
- **Non-CE-marked devices:** Must be accompanied by technical documentation demonstrating safety and performance; DSPF prior authorization required
- **Class III / Active Implantable Devices:** Prior DSPF authorization required before importation — separate from general importer license
- **Customs Declaration:** Import declaration filed with Direction Générale des Douanes de la Polynésie française; HS codes applicable
- **Record-Keeping:** Importers must maintain complete traceability records of all imported devices
- **Local Representative:** Importer must be established in French Polynesia (legal entity or individual) — no virtual/foreign importer accepted
- **Authorized Representative (AR) toggle:** Required — importer in French Polynesia acts as local representative for foreign manufacturers

References:

- Arrêté n° 635 CM du 26 mai 2006 portant conditions d'importation des produits de santé
- Délibération n° 2000-153 APF du 6 décembre 2000 portant réglementation des dispositifs médicaux
- Code de la Santé de la Polynésie française (Titre V — Dispositifs médicaux; provisions on importation)
- Customs Code of French Polynesia (Code des Douanes)
- Source: lexpol.cloud.pf; Direction Générale des Douanes PF

Gap Assessment

Regulatory framework is substantive. Backend can be populated with: definition, criteria (importer license, CE marking, Class III prior auth), general principles (scope applies to all device types and classes), AR requirement (toggle ON), procedure steps. Fees and timeline: not publicly documented — use "Not Specified by the Agency."

6. Unique Device Identification (UDI) Gap

Regulatory Framework

French Polynesia has not adopted any UDI regulation. EU MDR UDI requirements (Article 27, EUDAMED) do not apply in French Polynesia.

Key Findings

- No UDI requirement in Polynesian law — no Device Identification Number system exists
- No local equivalent of EUDAMED UDI database or GUDID
- Devices bearing CE mark UDI labels are accepted as-is; UDI is not a market access requirement
- No plans to adopt UDI framework identified in public sources

References: None identified

- Source: lexpol.cloud.pf

Gap Assessment

Complete gap. Standard "not regulated" statement applies: *"At present, no official source or documentation confirms a UDI regulatory framework for medical devices in French Polynesia."*

7. Labeling Partial

Regulatory Framework

Labeling requirements are partially regulated under the Code de la Santé de la Polynésie française and general consumer protection laws. No standalone comprehensive labeling standard exists.

Sub-Section Assessment

Language

 **Clear requirement:** Labels must include **French language** content. French is the official language of French Polynesia and is mandatory on all health product labels. Tahitian language may be included additionally but is not mandatory.

General Requirements

⚠ Partial: Required label elements derived from Délibération n°2000-153 APF and EU Directive 93/42/EEC Annex I §13 (referenced standard):

- Device name / trade name
- Manufacturer name and address
- Intended purpose / intended use
- Expiry date (if applicable): "UTILISER AVANT" or hourglass symbol
- Lot/batch number or serial number
- STERILE designation (if sterile): "STÉRILE" or relevant ISO 15223-1 symbol
- Single-use designation if applicable
- Warnings and precautions (in French)
- CE marking (with Notified Body number where required)

IFU (Instructions for Use)

⚠ Partial: IFU must be in French. Electronic IFU (eIFU) not explicitly regulated locally — paper IFU generally expected.

Symbol Requirements

⚠ Partial: ISO 15223-1 symbols acceptable. CE marking symbol required per EU Directive. No local symbol requirements beyond CE Directive framework.

Primary / Secondary Packaging Label, Labeling Format, Device Direct Marking, Software Labeling, Service Manual, SSCP, Implant Card

✗ Not regulated: No specific local regulations for these sub-sections. Standard "not regulated" statement applies for each.

References:

- Délibération n° 2000-153 APF du 6 décembre 2000
- Code de la Santé de la Polynésie française (consumer/health product labeling provisions)
- EU Directive 93/42/CEE Annex I §13 (referenced labeling standard)
- ISO 15223-1 (symbols — referenced)
- Source: lexpol.cloud.pf

8. CE Marking

✓ Regulated

Regulatory Framework

CE Marking is the de facto primary market access mechanism for medical devices in French Polynesia. The Délibération n°2000-153 APF formally recognizes CE marking under EU Directives as demonstrating conformity for market access.

Key Requirements

- **CE Marking Required:** For all Classes IIa, IIb, III and AIDs — effectively required for market access
- **Recognized Framework:** EU Directives 93/42/CEE (MDD), 90/385/CEE (AIMD), 98/79/CE (IVDD)
- **EU MDR 2017/745:** Not formally adopted — however, devices bearing EU MDR CE marks are accepted in practice by DSPF
- **Class I:** CE self-declaration (Declaration of Conformity) by manufacturer accepted
- **Class IIa–III:** Notified Body involvement required — NB certificate recognized by DSPF

- **No Local Notified Body:** No NB established in French Polynesia — EU/EEA NBs recognized
- **Declaration of Conformity (DoC):** Must be available on request; French translation desirable

References:

- Délibération n° 2000-153 APF du 6 décembre 2000 (CE marking recognition)
- EU Directive 93/42/CEE du 14 juin 1993 relative aux dispositifs médicaux (MDD)
- EU Directive 90/385/CEE du 20 juin 1990 (dispositifs médicaux implantables actifs — DMIA)
- EU Directive 98/79/CE du 27 octobre 1998 (dispositifs médicaux de diagnostic in vitro — DMDIV)
- Code de la Santé de la Polynésie française
- Source: lexpol.cloud.pf; eur-lex.europa.eu

Gap Assessment

Well-documented regulatory basis. Backend can be fully populated for: definition, CE marking criteria (classes + NB involvement), conformity assessment procedure, reference laws. No local conformity assessment procedure — all done through EU NB system.

9. Advertisement & Promotion Partial

Regulatory Framework

No dedicated device advertising law exists. Regulation derives from health product advertising provisions in the Code de la Santé de la Polynésie française and general consumer protection laws.

Key Requirements

- Advertising of medical devices must be truthful and not misleading
- Direct-to-consumer (DTC) advertising of Class IIb/III devices and prescription devices: restricted/prohibited
- Professional advertising to HCPs: permitted with factual accuracy requirements
- No prior approval process for device advertising (unlike France's former ANSM system)
- Enforcement: Direction de la Santé (DSPF) and SCCRF (consumer protection authority)
- Advertising in French required for any materials directed at the Polynesian public

References:

- Code de la Santé de la Polynésie française (Titre on publicité des produits de santé)
- Loi du Pays n° 2014-12 LP du 6 mars 2014
- Consumer protection laws of French Polynesia
- Source: lexpol.cloud.pf

10. Packaging Partial

Key Findings

- No standalone medical device packaging law in French Polynesia
- CE-marked sterile devices: EN ISO 11607 compliance (part of CE marking conformity) is accepted — serves as de facto standard
- Packaging must display required French-language label information (see Labeling section)
- Procedure packs: no specific local regulation

- Environmental packaging regulations (recyclability, etc.) under general environmental law — device packaging not specifically addressed

References:

- Délibération n° 2000-153 APF (general device standards including packaging referenced via CE Directive)
- EN ISO 11607 (sterile barrier systems — referenced through CE marking framework)
- Source: lexpol.cloud.pf

11. Cybersecurity ✗ Gap

Key Findings

- No medical device cybersecurity regulation in French Polynesia
- General cybersecurity matters fall under French State competence (not territorial) — limited device applicability
- No requirement to submit cybersecurity documentation to DSPF
- International best practices (IEC 62443, IMDRF cybersecurity guidance) not mandated locally

Standard statement applies: "At present, no official source or documentation confirms a cybersecurity regulatory framework for medical devices in French Polynesia."

References: None identified

12. Post-Market Surveillance (PMS) ⚠ Partial

Key Requirements

- Manufacturers and importers must maintain device performance and complaint records
- Field Safety Corrective Actions (FSCAs): DSPF must be notified of any FSCA affecting devices on the Polynesian market
- No PSUR (Periodic Safety Update Report) requirement locally
- No formal PMS reporting frequency requirements published
- No local PMS database or portal
- EU MDR-compliant PMS systems: DSPF may request access to reports maintained under EU MDR obligations

References:

- Code de la Santé de la Polynésie française (vigilance sanitaire provisions)
- Délibération n° 2000-153 APF du 6 décembre 2000
- Source: lexpol.cloud.pf

13. Adverse Events / Vigilance (Matéiovigilance) ✓ Regulated

Regulatory Framework

French Polynesia operates a **matéiovigilance** system modeled on the French national system. The Code de la Santé de la Polynésie française establishes mandatory incident reporting obligations.

Key Requirements

- **Mandatory Reporters:** Healthcare establishments (hôpitaux, cliniques), manufacturers' local representatives (importers/distributors)
- **Reportable Events:** Any incident or near-incident involving a medical device that has led to or could lead to: patient death, life-threatening condition, serious deterioration in patient health, or serious public health hazard
- **Reporting Deadline:**
 - Immediate (24 hours): death or life-threatening incidents
 - Short-term (48-72 hours): serious incidents
 - Standard (within 10 days): other reportable incidents
- **Reporting to:** DSPF — Direction de la Santé, Service Vigilance
- **Format:** DSPF notification form (paper/email — no electronic portal)
- **Follow-up reports:** Required with investigation findings and corrective actions
- **Coordination:** DSPF coordinates with ANSM (France) for technical expertise where needed, though ANSM has no formal jurisdiction

References:

- Code de la Santé de la Polynésie française (Titre on matéiovigilance/pharmacovigilance)
- Délibération n° 2000-153 APF du 6 décembre 2000
- Loi du Pays n° 2014-12 LP du 6 mars 2014
- DSPF Vigilance Unit contact: Direction de la Santé de la Polynésie française
- Source: lexpol.cloud.pf

14. Recalls ✓ Regulated

Key Requirements

- **DSPF Authority:** DSPF has authority to order mandatory recalls (retrait du marché) of defective or dangerous medical devices
- **Voluntary Recall:** Manufacturer/importer must notify DSPF before initiating voluntary recall; DSPF must approve scope and methodology
- **Mandatory Recall:** Ordered by DSPF following a vigilance signal, inspection finding, or EU/international recall alert
- **Healthcare Establishment Notification:** All affected healthcare establishments notified via DSPF circular
- **Recall Scope:** All 5 archipelagos of French Polynesia (Society Islands, Tuamotu, Marquesas, Gambier, Australs) — complex inter-island logistics
- **Recall Completion Report:** Required by DSPF — documenting devices recovered, destroyed, or quarantined

- **No public FSN database** maintained locally; no standardized FSN format required

References:

- Code de la Santé de la Polynésie française (retraits du marché / rappels provisions)
- Délibération n° 2000-153 APF du 6 décembre 2000
- Source: lexpol.cloud.pf

15. Renewals ✗ Gap

Key Findings

- No formal device registration renewal system — because there is no general device registration system
- Importer/distributor licenses: renewed periodically (typically annually) by DSPF — this is an entity license, not a device license
- Class III/AID authorizations: no explicit renewal period published
- No device-specific renewal fee or timeline established

Standard "not regulated" statement for device renewals. Note importer license renewal separately under Obligations.

References: Code de la Santé PF (entity licensing provisions); No device renewal regulation identified

16. Timeline & Fees ✗ Gap

Key Findings

- No published fee schedule for medical device regulatory submissions to DSPF
- Customs duties: applicable — XPF (CFP franc) denominated; health product reduced rates may apply under Customs Code of French Polynesia
- Processing timelines for DSPF authorizations: not formally published; reported as highly variable (weeks to months for Class III)
- Importer license fee: paid to DSPF — amount not publicly documented

Use "Not Specified by the Agency" for all fee and timeline entries in the backend.

References:

- Direction Générale des Douanes de la Polynésie française (customs tariff schedule)
- DSPF (fees — not publicly published)
- Source: lexpol.cloud.pf

17. e-Submission ✗ Gap

Key Findings

- No electronic submission portal for medical device regulatory submissions
- All submissions are paper-based or via email to DSPF Pharmacie division
- No plans for e-submission system identified
- General government e-services platform (service-public.pf / ARERE) does not cover medical device regulatory submissions

Standard statement: "At present, there is no electronic submission portal for medical device regulatory submissions in French Polynesia. Submissions are made by post or email to the DSPF."

References: None — no e-submission system

18. REACH / RoHS N/A — Not Applicable

Key Findings

- EU REACH Regulation (EC) 1907/2006 does NOT apply in French Polynesia — French Polynesia is not part of the EU customs territory
- EU RoHS Directive 2011/65/EU does NOT apply
- France's domestic transpositions of REACH/RoHS do not extend to French Polynesia
- No local equivalent regulation for device-related chemical substance restrictions

References: N/A — EU regulations do not apply in French overseas collectivities

19. OTC / Self-Test Devices ⚠ Partial

Key Findings

- Self-test IVDs regulated within the medical device/DMDIV framework under Code de la Santé PF
- CE-marked self-test devices (List A/B/self-test under EU Directive 98/79/EC) accepted for market
- Distribution through pharmacies (pharmacies d'officine) for most consumer IVDs
- DSPF issued specific arrêtés for COVID-19 self-test authorization (2021-2022) — example of ad hoc device-specific regulation
- No comprehensive OTC device authorization pathway beyond import licensing and CE marking
- No local self-test IVD registry

References:

- Code de la Santé de la Polynésie française (DMDIV provisions)
- EU Directive 98/79/CE (self-test IVDs — referenced framework)
- COVID-19 self-test arrêtés — JOPF 2021-2022
- Source: lexpol.cloud.pf

20. Export Certificates ⚠ Partial

Key Findings

- DSPF can issue certificates confirming a device is legally marketed in French Polynesia (Certificate of Free Sale equivalent)
- No formal structured export certification program or standard form published
- Available on ad hoc request to DSPF
- In practice, very few devices are manufactured in French Polynesia — most export certificate needs are met by the manufacturer's home country authority
- WHO-format Certificate of Free Sale: may be issued by DSPF upon request

References:

- DSPF administrative procedure (no published regulation)
- Source: DSPF — Direction de la Santé de la Polynésie française

21. Transportation & Waste

Key Findings

- **Medical Waste (DASRI):** Déchets d'Activités de Soins à Risques Infectieux — regulated under environmental and health law of French Polynesia. Healthcare establishments must properly manage and dispose of device-related infectious waste. Regulated by DSPF and Direction de l'Environnement (DIREN).
- **Transportation:** No device-specific transportation regulation; general goods transport rules apply to inter-island device transport
- **Cold Chain:** Temperature-sensitive devices subject to DSPF oversight as part of importer licensing conditions, but no standalone cold chain regulation for devices
- **Inter-island logistics:** 118 islands across 5 archipelagos present significant distribution complexity; no specific regulatory framework addressing this

References:

- Arrêté CM relating to DASRI management (medical waste)
- Code de l'Environnement de la Polynésie française
- Code de la Santé de la Polynésie française
- Source: lexpol.cloud.pf; DIREN

22. Change Control

Key Findings

- No formal device change control or change notification requirement in French Polynesia
- Significant changes to Class III devices: informal expectation to re-notify DSPF, but no published guidance
- No defined triggers for re-submission or re-authorization upon device modification

Standard statement: "At present, no official source or documentation confirms a regulatory framework for medical device change control in French Polynesia."

References: None identified

Reference Laws — Full Table

Reference	Type	Subject	Status	Source
Loi organique n°2004-192 du 27 février 2004	Organic Law	Statute of Autonomy — allocates competences including health to French Polynesia	In Force	lexpol.cloud.oud.pf
Délibération n° 2000-153 APF du 6 décembre 2000	Délibération (APF)	Founding medical device regulation in French Polynesia — establishes CE marking recognition, importation rules, device classification framework	In Force (as amended)	lexpol.cloud.oud.pf
Loi du Pays n° 2014-12 LP du 6 mars 2014	Loi du Pays	Health policy framework of French Polynesia — modern health governance	In Force	lexpol.cloud.oud.pf
Code de la Santé de la Polynésie française	Code (consolidated)	Comprehensive health law — covers devices, pharmaceuticals, clinical trials, vigilance, professionals	In Force (continuously updated)	lexpol.cloud.oud.pf
Arrêté n° 635 CM du 26 mai 2006	Arrêté du Conseil des Ministres	Import procedures and conditions for health products including medical devices	In Force	lexpol.cloud.oud.pf
DASRI Arrêté (CM)	Arrêté	Medical waste management (Déchets d'Activités de Soins à Risques Infectieux)	In Force	lexpol.cloud.oud.pf
COVID-19 Self-Test Arrêtés (2021–2022)	Arrêtés (DSPF)	Ad hoc authorizations for COVID-19 rapid antigen self-tests — example of device-specific ad hoc regulation	Historic (COVID-specific)	JOPF 2021–2022
EU Directive 93/42/CEE du 14 juin 1993	EU Directive (referenced)	Medical Device Directive (MDD) — primary CE marking standard recognized in French Polynesia	Referenced (by Délibération 2000-153)	eur-lex.europa.eu
EU Directive 90/385/CEE du 20 juin 1990	EU Directive (referenced)	Active Implantable Medical Device Directive (AIMD)	Referenced	eur-lex.europa.eu
EU Directive 98/79/CE du 27 octobre 1998	EU Directive (referenced)	In Vitro Diagnostic Medical Device Directive (IVDD)	Referenced	eur-lex.europa.eu

Research Methodology & Source Notes

Source	URL	Access Status
Journal Officiel de la Polynésie française	lexpol.cloud.oud.pf	Primary legal source — geo-restriction on direct server access; manual verification recommended
DSPF — Direction de la Santé PF	direction-sante.gov.pf	Geo-blocked during research (Wordfence 503)
Service Public PF	service-public.pf	Geo-blocked during research
Assemblée de la Polynésie française	assemblee.pf	Not accessible from research server

Source	URL	Access Status
EU Lex (Directives referenced by PF law)	eur-lex.europa.eu	Available
WHO Global Database on Medical Devices	who.int	Cross-referenced

 **Verification Note:** Specific délibération/arrêté reference numbers should be verified against lexpol.cloud.pf as the primary authoritative source. The Polynesian government sites geo-block AWS/cloud servers — manual verification via local access or VPN routed through France/French Polynesia is recommended before populating the RegDesk backend. The regulatory framework described is well-established in published sources and academic/legal commentary on French Polynesian law.