

French Polynesia — Medical Device Regulatory Gap Assessment

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**Framework:** WI\_551 RegDesk Backend System Work Instruction Version 4

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

**Source:** Lexpol.cloud.pf (Journal Officiel de la Polynésie française), DSPF, ANSM France

**⚠ Critical Jurisdictional Note:** French Polynesia is a *collectivité d'outre-mer* (overseas collectivity) governed by Article 74 of the French Constitution, with a broad autonomous statute dating from 2004 (Loi organique n° 2004-192 du 27 février 2004). Health is a competence **transferred to the Polynesian government** — French metropolitan health laws (including ANSM jurisdiction and EU MDR) do **NOT automatically apply** to French Polynesia. Medical devices are regulated under local Polynesian laws adopted by the *Assemblée de la Polynésie française* and published in the *Journal Officiel de la Polynésie française (JOPF)*. The EU MDR (2017/745) does **not apply**. France's national Code de la santé publique applies only where explicitly extended by an *ordonnance* or loi de ratification. The primary reference legislation is the **Code de la santé de la Polynésie française** (LP n° 2018-29 of 8 November 2018 and amendments).

Executive Summary — Gap Status by Section

| Section                             | Status    | Data Available | Key Gap / Note                                                                              |
|-------------------------------------|-----------|----------------|---------------------------------------------------------------------------------------------|
| Device Classification               | REGULATED | Partial        | 4-class system modelled on French system; DSPF confirmation needed                          |
| Market Authorization / Registration | UNCLEAR   | Low            | No formal pre-market approval system identified; rely on CE marking + import notification   |
| QMS                                 | UNCLEAR   | Low            | No local QMS decree confirmed; GMP/ISO 13485 implicitly accepted via CE marking recognition |
| Clinical Trials                     | REGULATED | Partial        | Local code references; research on clinical investigations limited                          |
| Importation                         | REGULATED | Moderate       | Import controls via Direction des affaires économiques; DSPF health check at entry          |
| UDI                                 | GAP       | None           | No UDI system exists in French Polynesia; no local legislation found                        |
| Labeling — General                  | REGULATED | Moderate       | French language required; CE/local requirements apply                                       |
| Labeling — Language                 | REGULATED | Confirmed      | French (required); Tahitian may supplement                                                  |
| Labeling — Primary Packaging        | UNCLEAR   | Low            | No specific local rules confirmed beyond French language requirement                        |
| Labeling — Secondary Packaging      | UNCLEAR   | Low            | Same as above                                                                               |

| Section                   | Status    | Data Available | Key Gap / Note                                                                                       |
|---------------------------|-----------|----------------|------------------------------------------------------------------------------------------------------|
| Labeling — IFU            | UNCLEAR   | Low            | French language required; no specific local IFU law confirmed                                        |
| Labeling — e-IFU          | GAP       | None           | No local e-IFU regulation identified                                                                 |
| Labeling — Symbols        | UNCLEAR   | Low            | ISO 15223-1 likely referenced through CE marking requirements                                        |
| CE Marking                | REGULATED | Moderate       | CE marking recognized/required for devices placed on market; but local conformity assessment unclear |
| Advertisement & Promotion | UNCLEAR   | Low            | Health code provisions exist; specific ad/promo rules for MDs not confirmed                          |
| Packaging                 | UNCLEAR   | Low            | No specific local packaging decree for MDs confirmed                                                 |
| Cybersecurity             | GAP       | None           | No local cybersecurity regulation for MDs                                                            |
| PMS                       | UNCLEAR   | Low            | DSPF oversees health product safety; no formal PMS framework confirmed                               |
| Adverse Events            | REGULATED | Partial        | Health code requires notification to DSPF; no dedicated MD vigilance decree found                    |
| Recalls                   | REGULATED | Partial        | DSPF may issue withdrawal orders; no formal recall procedure codified for MDs                        |
| Renewals                  | GAP       | None           | No renewal process identified (no pre-market approval system confirmed)                              |
| Timeline & Fees           | GAP       | None           | No formal fee schedule identified for MD services                                                    |
| e-Submission              | GAP       | None           | No electronic portal for MD submissions identified                                                   |
| Battery Requirements      | GAP       | None           | No specific local battery regulation for MDs confirmed                                               |
| Shelf-Life                | UNCLEAR   | Low            | General health product requirements; no specific MD shelf-life rule                                  |
| REACH / RoHS              | GAP       | None           | EU REACH/RoHS do NOT apply; no equivalent local regulation confirmed                                 |
| Change Control            | GAP       | None           | No change control regulation for MDs identified                                                      |
| OTC                       | UNCLEAR   | Low            | OTC concept likely applies; no specific MD OTC regulation confirmed                                  |
| Export Certificates       | UNCLEAR   | Low            | No specific export certificate requirement for MDs found                                             |
| Transportation / Storage  | UNCLEAR   | Low            | General health code transport requirements; no specific MD rule                                      |
| Waste / WEEE              | UNCLEAR   | Low            | Local environmental laws apply; no WEEE-equivalent for MDs confirmed                                 |

## Jurisdictional Framework

**Legal basis for autonomy:** Loi organique n° 2004-192 du 27 février 2004 portant statut d'autonomie de la Polynésie française (as amended). Under Article 31 of this statute, *santé publique* (public health) is a transferred competency — French Polynesia governs its own health laws independently. The French Code de la santé publique and ANSM authority do NOT extend here unless specifically extended by act of the French Parliament.

**Primary MD legislation:** The health of French Polynesia is governed through the *Code de la santé de la Polynésie française*, adopted progressively by the Assemblée de la Polynésie française. Medical devices fall

under general health product provisions of this code. The relevant sections are enacted through *lois du pays* (LP) and *arrêtés* published in the JO PF.

**EU MDR status:** The EU Medical Device Regulation (EU) 2017/745 does NOT apply. CE marking is, however, widely recognised as a standard of quality for imported devices, and products may need to carry CE marking if they are manufactured in or imported from the EU/EEA.

**Regulatory authority:** *Direction de la Santé de la Polynésie française* (DSPF / Direction de la Santé) — the main public health authority under the Polynesian Ministry of Health.

## Section-by-Section Gap Assessment

### 1. Device Classification REGULATED — PARTIAL DATA

**Status:** French Polynesia follows a device classification framework that mirrors the French/EU model, given the historical alignment of its health system with French metropolitan practice. Devices are categorised by risk level.

#### Available Information

- Classification broadly follows 4 classes: Class I (low risk), Class IIa (medium-low), Class IIb (medium-high), Class III (high risk), aligned with historical French practice prior to EU MDR.
- In-vitro diagnostic devices (IVDs) classified separately.
- DSPF is the competent authority for classification determinations.
- Active implantable devices treated as high-risk (Class III equivalent).

#### Laws & References

| Title                                                                      | Reference                                         | Type          | URL                                                        |
|----------------------------------------------------------------------------|---------------------------------------------------|---------------|------------------------------------------------------------|
| Code de la santé de la Polynésie française — Livre III (produits de santé) | LP n° 2018-29 du 8 novembre 2018 et modifications | Loi du Pays   | <a href="http://lexpol.clou.d.pf">lexpol.clou.d.pf</a>     |
| Loi organique portant statut d'autonomie de la Polynésie française         | Loi organique n° 2004-192 du 27 février 2004      | Loi organique | <a href="http://legifrance.gouv.fr">legifrance.gouv.fr</a> |

**Gap:** Exact classification criteria and class definitions published in local JOPF texts have not been independently verified from live source. Confirmation from DSPF needed. No specific Arrêté on device classification identified in available searches.

### 2. Market Authorization / Registration UNCLEAR

**Status:** No formal pre-market approval or registration system for medical devices has been confirmed for French Polynesia. The system appears to rely primarily on CE marking as a quality proxy, with import notification obligations through customs/Direction des affaires économiques.

#### Available Information

- Devices bearing CE marking (or equivalent conformity mark) may be placed on the market without separate Polynesian pre-market authorisation.
- Importers and distributors must register with commercial authorities; no separate device register confirmed.
- DSPF may require notification or documentation for certain high-risk devices or novel technologies.

- Class III / active implantable devices may face stricter DSPF scrutiny at importation.
- No FIMEA-/TGA-/ANVISA-style device register found for French Polynesia.

## Laws & References

| Title                                                                                                     | Reference                  | Type        | URL                                                    |
|-----------------------------------------------------------------------------------------------------------|----------------------------|-------------|--------------------------------------------------------|
| Code de la santé de la Polynésie française — dispositions sur la mise sur le marché des produits de santé | LP n° 2018-29 (as amended) | Loi du Pays | <a href="http://lexpol.clo-ud.pf">lexpol.clo-ud.pf</a> |
| Réglementation des importations — Direction des affaires économiques                                      | Arrêtés DAE                | Arrêté      | <a href="http://dae.gov.pf">dae.gov.pf</a>             |

**Gap:** No confirmed pre-market registration pathway. Await DSPF confirmation on whether high-risk MDs (Class III, active implantables) require separate authorisation before market placement. This is a significant research gap that requires direct DSPF contact.

## 3. Quality Management System (QMS) UNCLEAR

**Status:** No specific QMS regulation (equivalent to ISO 13485 requirement or GMP decree for medical devices) has been identified in local Polynesian law. Quality requirements are implicitly tied to CE marking requirements for imported devices.

### Available Information

- ISO 13485 compliance is implicitly expected for manufacturers who hold CE marking (required by EU MDR/MDD for CE certification) — but this is not a locally enacted QMS requirement.
- DSPF inspections of healthcare facilities may cover quality aspects of medical devices in use.
- No local QMS certification requirement for manufacturers or importers has been identified.
- MDSAP: Not applicable — French Polynesia does not participate in MDSAP.

**Gap:** No local QMS regulation confirmed. Significant gap — requires contacting DSPF to confirm if any QMS or GMP requirements are imposed on importers, distributors, or manufacturers selling into French Polynesia.

## 4. Clinical Trials REGULATED — PARTIAL DATA

**Status:** French Polynesia has provisions for clinical research / biomedical research under its health code. Research involving human subjects requires ethical review and authorisation from the DSPF.

### Available Information

- Biomedical research on human subjects is regulated under the Code de la santé de la Polynésie française.
- An ethics committee (*Comité de protection des personnes* equivalent, or referral to metropolitan committee) reviews research protocols.
- Investigators must hold appropriate qualifications; sponsor responsibilities apply.
- Clinical investigations of medical devices (as distinct from drug trials) have limited specific local provisions — gap exists.
- PMCF studies and Post-Market Clinical Follow-Up: no local framework confirmed.

## Laws & References

| Title                                                                | Reference                                                            | Type        | URL                                                    |
|----------------------------------------------------------------------|----------------------------------------------------------------------|-------------|--------------------------------------------------------|
| Code de la santé de la Polynésie française — recherches biomédicales | LP n° 2018-29 (Livre III, recherches impliquant la personne humaine) | Loi du Pays | <a href="http://lexpol.clo-ud.pf">lexpol.clo-ud.pf</a> |
| Arrêté relatif aux recherches biomédicales — DSPF                    | Various arrêtés (JOPF)                                               | Arrêté      | <a href="http://lexpol.clo-ud.pf">lexpol.clo-ud.pf</a> |

**Gap:** No dedicated clinical investigation regulation for medical devices found. General biomedical research law applies. Device-specific clinical investigation requirements (performance studies, PMCF, CER) not specifically addressed in local law. Direct DSPF enquiry required.

## 5. Importation REGULATED — MODERATE DATA

**Status:** Medical device importation is regulated. French Polynesia controls imports through customs and the Direction des affaires économiques (DAE). Health product imports require DSPF clearance for certain categories.

### Available Information

- Imports require customs declarations through French Polynesia's own customs authority (separate from French metropolitan customs — but aligned with French customs tariff nomenclature).
- Specific health products, including medical devices, may require prior authorisation or notification from DSPF before importation.
- Importers must be duly registered commercial entities in French Polynesia.
- Customs tariff: French Polynesia has its own tariff schedule (not EU CET). Medical device HS codes generally benefit from 0% import duty under WHO/health product provisions, but local rates must be confirmed.
- Temporary importation for clinical use or demonstration may be permitted under special conditions.
- An Authorized Representative (AR) in French Polynesia may be required for non-resident manufacturers — not confirmed by local law.

### Laws & References

| Title                                                                                          | Reference                  | Type        | URL                                                    |
|------------------------------------------------------------------------------------------------|----------------------------|-------------|--------------------------------------------------------|
| Code des douanes de la Polynésie française                                                     | LP applicable, JOPF        | Loi du Pays | <a href="http://lexpol.clo-ud.pf">lexpol.clo-ud.pf</a> |
| Réglementation des importations de produits de santé — DAE                                     | Arrêtés DAE, JOPF          | Arrêté      | <a href="http://dae.gov.pf">dae.gov.pf</a>             |
| Code de la santé de la Polynésie française — conditions d'importation des dispositifs médicaux | LP n° 2018-29 (as amended) | Loi du Pays | <a href="http://lexpol.clo-ud.pf">lexpol.clo-ud.pf</a> |

## 6. Unique Device Identification (UDI) GAP — NO REGULATION

**Status:** No UDI system exists in French Polynesia. The EU's UDI/EUDAMED system does not apply. No local law or regulation requiring UDI labelling or registration has been identified.

**Gap:** Complete regulatory gap. UDI requirements are absent. Devices imported from the EU/EEA that already carry EU UDI markings may retain them, but there is no local legal requirement. Recommend: "At present, no official source or documentation confirms the regulatory framework for UDI requirements in French Polynesia."

## 7. Labeling REGULATED — MODERATE DATA

### 7a. General Requirements

Medical device labels must meet general health product requirements under the Code de la santé de la Polynésie française. Devices must provide sufficient information for safe use. CE marking requirements serve as a de facto baseline for imported devices.

### 7b. Language Requirements CONFIRMED

**Required language: French.** French is the official language of French Polynesia under the Loi organique. All labelling, IFU, and user documentation must be in French. Tahitian (reo Mā'ohi) is a co-official language but not required for medical device labelling.

### 7c. Primary Packaging Label

Must include at minimum: device name, manufacturer details, lot/serial number, expiry date (if applicable), sterility indicators (if applicable), CE marking (for EU-manufactured devices), storage conditions, and warnings — consistent with French CE marking practice.

### 7d. Secondary Packaging Label

Same general requirements as primary packaging; IFU reference; quantity.

### 7e. IFU (Instructions for Use)

Must be provided in French. General health product requirements apply. No specific local IFU decree confirmed beyond language requirement.

### 7f. e-IFU GAP

No local e-IFU regulation identified. EU Commission Regulation (EU) 207/2012 on e-IFU does not apply.

### 7g. Symbol Requirements

ISO 15223-1 symbols are widely used and likely recognised, particularly for imported devices. No local standard mandating specific symbols beyond CE marking confirmed.

## Laws & References

| Title                                                                         | Reference                                    | Type          | URL                                                         |
|-------------------------------------------------------------------------------|----------------------------------------------|---------------|-------------------------------------------------------------|
| Loi organique portant statut d'autonomie — officialisation du français        | Loi organique n° 2004-192 du 27 février 2004 | Loi organique | <a href="https://legifrance.gouv.fr">legifrance.gouv.fr</a> |
| Code de la santé de la Polynésie française — étiquetage des produits de santé | LP n° 2018-29 (as amended)                   | Loi du Pays   | <a href="https://lexpol.clou.d.pf">lexpol.clou.d.pf</a>     |
| Loi constitutionnelle relative à la Polynésie française — langue officielle   | Art. 57 de la loi organique 2004-192         | Loi organique | <a href="https://lexpol.clou.d.pf">lexpol.clou.d.pf</a>     |

## 8. CE Marking / Conformity Assessment REGULATED — MODERATE DATA

**Status:** CE marking is recognised in French Polynesia as evidence of conformity for medical devices imported from the EU/EEA. However, CE marking is not legally mandated by local law for all devices — its recognition is practical/customary rather than legislative.

### Available Information

- Devices with CE marking under the EU Medical Device Directive (93/42/EEC, now transitioning per EU MDR) are generally accepted without separate conformity assessment.
- No local Notified Body exists in French Polynesia.
- Conformity assessment is performed by EU Notified Bodies; certificates issued in EU are recognised.
- For devices without CE marking (e.g., from non-EU countries), DSPF may require additional documentation to demonstrate safety and performance.
- No specific local conformity assessment pathway has been established.

### Laws & References

| Title                                                                         | Reference                  | Type        | URL                                                    |
|-------------------------------------------------------------------------------|----------------------------|-------------|--------------------------------------------------------|
| Code de la santé de la Polynésie française — conditions de mise sur le marché | LP n° 2018-29 (as amended) | Loi du Pays | <a href="http://lexpol.clou.d.pf">lexpol.clou.d.pf</a> |

**Gap:** No explicit legislation mandating CE marking or defining an alternative conformity pathway for non-CE-marked devices has been confirmed. DSPF contact needed to clarify requirements for devices from non-EU markets (USA, Japan, China, etc.).

## 9. Advertisement & Promotion UNCLEAR

**Status:** General advertising rules under French Polynesia's commercial and health laws apply. No specific medical device advertising regulation confirmed.

### Available Information

- Health product advertising is subject to general health code provisions — claims must not be misleading.
- Direct-to-consumer advertising of high-risk medical devices is likely restricted, consistent with French practice.
- No DSPF pre-approval process for MD advertising confirmed.

**Gap:** No specific advertisement and promotion regulation for medical devices identified. Requires DSPF confirmation. Standard statement to apply: "At present, no official source or documentation confirms the regulatory framework for Advertisement and Promotion of medical devices in French Polynesia."

## 10. Packaging UNCLEAR

No specific medical device packaging regulation confirmed in local law. CE marking requirements (which include packaging requirements per EU MDD/MDR Annex I) serve as a de facto baseline for imported devices. Sterile packaging must comply with applicable ISO standards (ISO 11607).

**Gap:** No local packaging decree for medical devices identified. Recommend applying: "At present, no official source confirms specific packaging regulations for medical devices in French Polynesia beyond the general requirements implied by CE marking acceptance."

## 11. Cybersecurity GAP — NO REGULATION

No cybersecurity regulation for medical devices identified in French Polynesia. The EU MDR Article 18 (implant card + cybersecurity) and MDCG guidance documents do not apply locally.

**Gap:** Complete regulatory gap. No local cybersecurity requirements for medical devices. Recommend standard "no framework" statement for this section.

## 12. Post-Market Surveillance (PMS) UNCLEAR

**Status:** DSPF oversees health product safety in the market. No formal PMS framework (PSURs, complaint handling, FSN/FSCA tracking) has been confirmed by local legislation for medical devices.

### Available Information

- DSPF has general powers to monitor health products and take corrective action.
- No local requirement for manufacturers to submit PSURs, periodic safety reports, or formal complaint logs to DSPF.
- FSN/FSCA: No local procedure confirmed — manufacturers issuing EU FSNs/FSCAs should voluntarily notify DSPF.

**Gap:** No formal PMS framework. Requires DSPF contact to confirm what PMS obligations (if any) are imposed on importers/distributors of MDs in French Polynesia.

## 13. Adverse Events / Vigilance Reporting REGULATED — PARTIAL DATA

**Status:** Health product vigilance is addressed in the Code de la santé de la Polynésie française. Healthcare providers and importers/distributors are expected to report serious incidents to DSPF.

### Available Information

- Serious adverse events involving medical devices should be reported to the DSPF.
- No dedicated matériovigilance decree (equivalent to French ANSM's matériovigilance system) has been confirmed for French Polynesia.
- DSPF contact for vigilance: Direction de la Santé, BP 611, Papeete, Tahiti.
- Reporting obligation applies to economic operators (importers, distributors) placing devices on the Polynesian market.

### Laws & References

| Title                                                                                           | Reference                  | Type        | URL                                                    |
|-------------------------------------------------------------------------------------------------|----------------------------|-------------|--------------------------------------------------------|
| Code de la santé de la Polynésie française — matériovigilance / vigilance des produits de santé | LP n° 2018-29 (as amended) | Loi du Pays | <a href="http://lexpol.clo-ud.pf">lexpol.clo-ud.pf</a> |

**Gap:** No dedicated matériovigilance decree confirmed. Timeline for reporting, reporting forms, and thresholds not confirmed from official source. DSPF contact required.

#### 14. Recalls

REGULATED — PARTIAL DATA

**Status:** DSPF has authority to order recall or withdrawal of unsafe health products. Voluntary recall by manufacturers/importers is also possible.

##### *Available Information*

- DSPF can issue withdrawal or recall orders for health products including medical devices when a safety risk is identified.
- No formal recall procedure (notification timelines, classes of recall) for MDs specifically confirmed.
- EU recall actions (FSCA) should be communicated to DSPF — no confirmed legal obligation to do so locally.

**Gap:** No formalized recall classification or procedure for MDs confirmed in local law. DSPF contact required for current practice.

#### 15. Renewals

GAP — NO REGULATION

Since no formal pre-market registration/authorization system has been confirmed, no renewal process exists. If a notification/authorization system is established in the future, renewal requirements would likely follow. Currently not applicable.

**Gap:** No renewal regulation identified. Linked to absence of pre-market registration system.

#### 16. Timeline & Fees

GAP — NO DATA

No official fee schedule for medical device-related DSPF services has been identified. Import customs duties (if any) are administered by Direction des affaires économiques.

**Gap:** No fee schedule confirmed for medical device regulatory services. DSPF contact required. Recommend: "Not Specified by the Agency" per WI\_551 rules.

#### 17. e-Submission

GAP — NO PORTAL

No electronic submission portal for medical devices has been identified for French Polynesia. DSPF manages filings by paper/email. No online regulatory system equivalent to EUDAMED, TGA portal, or CDSCO portal exists.

**Gap:** No e-submission system. All regulatory interactions are via physical correspondence or email to DSPF (Direction de la Santé, Papeete, Tahiti).

#### 18. Battery Requirements

GAP — NO REGULATION

No specific local battery regulation for medical devices confirmed. CE marking requirements (which include battery safety per applicable standards) serve as a de facto baseline for imported CE-marked devices. No local battery disposal regulation specific to MDs identified.

**Gap:** No local battery regulation for MDs. Standard "no framework" statement applies.

## 19. Shelf-Life **UNCLEAR**

General health code requirements on product expiry apply. No specific shelf-life regulation for medical devices (as distinct from pharmaceuticals) has been confirmed in local law. Expiry dates must appear on labels (implied by general health product labelling rules).

**Gap:** No specific MD shelf-life framework confirmed. General health product expiry date requirement applies.

## 20. REACH / RoHS / Environmental **GAP — NOT APPLICABLE**

EU REACH (Regulation EC 1907/2006) and EU RoHS Directive (2011/65/EU) do NOT apply to French Polynesia. No equivalent local chemical restriction legislation for medical devices has been identified. General environmental protection laws of French Polynesia apply to waste management but not specifically to MD chemical content.

**Gap:** REACH and RoHS are not applicable. No equivalent local regulation. Standard "not applicable" statement.

## 21. Change Control **GAP — NO REGULATION**

No change control regulation for medical devices has been identified in French Polynesia. Given the absence of a formal pre-market registration system, change notifications to a regulatory authority are not required.

**Gap:** No change control framework. Standard "no framework" statement applies.

## 22. Over-the-Counter (OTC) **UNCLEAR**

OTC medical devices (e.g., wound care, thermometers, pregnancy tests) are available in pharmacies and general retail in French Polynesia. No specific OTC-designation law for medical devices has been identified. Sales restrictions by device class may apply.

**Gap:** No OTC-specific MD regulation confirmed. General commercial and health product provisions apply. DSPF contact required to confirm any sales restriction lists.

## 23. Export Certificates **UNCLEAR**

Manufacturers based in French Polynesia seeking to export devices may require a Certificate of Free Sale or equivalent from DSPF. French Polynesia's small manufacturing base means this is a rare requirement. No confirmed export certificate procedure identified.

**Gap:** No confirmed export certificate procedure for MDs from French Polynesia. DSPF and DAE contact required.

## 24. Transportation / Storage UNCLEAR

General health code requirements on storage conditions for health products apply. Cold-chain requirements for temperature-sensitive devices are implied but no specific MD transportation regulation has been confirmed locally. IATA/ICAO dangerous goods regulations apply to air transport (French Polynesia uses Faa'a International Airport, Papeete).

**Gap:** No specific local MD transport/storage regulation confirmed beyond general health product rules and IATA for dangerous goods. DSPF contact required.

## 25. Waste Management / WEEE UNCLEAR

EU WEEE Directive does not apply. French Polynesia has its own environmental protection laws. Medical waste (including end-of-life medical devices, sharps, contaminated devices) is regulated under local environmental / public health rules. No WEEE-specific electronics recycling scheme for MDs confirmed.

### Laws & References

| Title                                                                   | Reference           | Type        | URL                                                    |
|-------------------------------------------------------------------------|---------------------|-------------|--------------------------------------------------------|
| Code de l'environnement de la Polynésie française — gestion des déchets | LP applicable, JOPF | Loi du Pays | <a href="http://lexpol.clou.d.pf">lexpol.clou d.pf</a> |
| Réglementation sur les déchets médicaux — DSPF                          | Arrêtés DSPF        | Arrêté      | <a href="http://lexpol.clou d.pf">lexpol.clou d.pf</a> |

**Gap:** Medical waste regulation exists but device-specific end-of-life/WEEE framework not confirmed. No electronics recycling obligation confirmed for MDs.

## Key Reference Legislation

| Title                                                                     | Reference                                           | Type                   | Date        | Scope                                                                                                       | URL                                                        |
|---------------------------------------------------------------------------|-----------------------------------------------------|------------------------|-------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| Loi organique portant statut d'autonomie de la Polynésie française        | Loi organique n° 2004-192                           | Loi organique (France) | 27 Feb 2004 | Establishes autonomous status; transfers health competence to Polynesian government                         | <a href="http://legifrance.gouv.fr">legifrance.gouv.fr</a> |
| Code de la santé de la Polynésie française                                | LP n° 2018-29 du 8 novembre 2018 (et modifications) | Loi du Pays            | 8 Nov 2018  | Primary health code: covers health products, clinical research, health product safety, health professionals | <a href="http://lexpol.clou d.pf">lexpol.clou d.pf</a>     |
| Loi du Pays relative aux activités pharmaceutiques en Polynésie française | LP n° 2011-19 (and amendments)                      | Loi du Pays            | 2011        | Pharmaceutical and health product distribution; pharmacies; importation of health products                  | <a href="http://lexpol.clou d.pf">lexpol.clou d.pf</a>     |

| Title                                                              | Reference              | Type          | Date       | Scope                                                                                      | URL                                |
|--------------------------------------------------------------------|------------------------|---------------|------------|--------------------------------------------------------------------------------------------|------------------------------------|
| Arrêtés portant organisation de la Direction de la Santé           | Various arrêtés (JOPF) | Arrêté        | Various    | Establishes DSPF mandate including health product surveillance                             | <a href="#">lexpo.l.clou.d.pf</a>  |
| Code des douanes de la Polynésie française                         | LP applicable          | Loi du Pays   | Various    | Import/export customs; tariff classification of medical devices                            | <a href="#">lexpo.l.clou.d.pf</a>  |
| Code de l'environnement de la Polynésie française                  | LP applicable          | Loi du Pays   | Various    | Waste management including medical waste                                                   | <a href="#">lexpo.l.clou.d.pf</a>  |
| EU Regulation (EU) 2017/745 (EU MDR) — FOR REFERENCE ONLY          | EU MDR                 | EU Regulation | 5 Apr 2017 | Does NOT apply in French Polynesia — reference only for CE-marked devices imported from EU | <a href="#">eur-lex.euro.pa.eu</a> |
| EU Medical Devices Directive 93/42/EEC (legacy, superseded by MDR) | MDD 93/42/EEC          | EU Directive  | 1993       | Does NOT apply — reference for legacy CE-marked devices from EU/EEA                        | <a href="#">eur-lex.euro.pa.eu</a> |

## Recommended Actions — DSPF Contact & Research Gaps

| #  | Action Required                                                                                       | Section(s) Affected                  | Priority                                     |
|----|-------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------------------|
| 1  | Contact DSPF to confirm if pre-market registration/notification is required for Class IIb/III devices | Market Authorization, Classification | <span style="color: red;">●</span> High      |
| 2  | Obtain full text of Code de la santé (LP n° 2018-29) medical device provisions from JOPF              | All sections                         | <span style="color: red;">●</span> High      |
| 3  | Confirm matériovigilance requirements and reporting form/timeline with DSPF                           | Adverse Events, Recalls, PMS         | <span style="color: red;">●</span> High      |
| 4  | Confirm import documentation requirements for high-risk MDs (Class III, active implantables)          | Importation                          | <span style="color: orange;">●</span> Medium |
| 5  | Confirm QMS/GMP requirements imposed on importers or distributors in French Polynesia                 | QMS                                  | <span style="color: orange;">●</span> Medium |
| 6  | Verify classification framework against current DSPF guidance or published decree                     | Classification                       | <span style="color: orange;">●</span> Medium |
| 7  | Confirm advertisement and promotion requirements for MDs                                              | Advertisement & Promotion            | <span style="color: yellow;">●</span> Low    |
| 8  | Confirm if any fee schedule applies for DSPF health product services                                  | Timeline & Fees                      | <span style="color: yellow;">●</span> Low    |
| 9  | Confirm customs duty rates applicable to medical device HS codes                                      | Importation, Timeline & Fees         | <span style="color: yellow;">●</span> Low    |
| 10 | Confirm medical waste / end-of-life device disposal obligations                                       | Waste / WEEE                         | <span style="color: yellow;">●</span> Low    |

## Regulatory Authority Contact

| Authority                    | Full Name                                       | Address                                         | Contact                                                                                                      | Website                                 |
|------------------------------|-------------------------------------------------|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| DSPF / Direction de la Santé | Direction de la Santé de la Polynésie française | BP 611, 98713 Papeete, Tahiti, French Polynesia | Email: <a href="mailto:dspf@sante.gov.pf">dspf@sante.gov.pf</a> (verify)   Tel: +689 40 48 00 00 (DSPF main) | <a href="#">hygiene-publique.gov.pf</a> |
| DAE                          | Direction des affaires économiques              | Papeete, Tahiti                                 | For import/trade regulations                                                                                 | <a href="#">dae.gov.pf</a>              |

