COMPLIANCE · SAFETY · LABELLING · REFERENCE DOCUMENT · PUBLIC

Product safety and certification

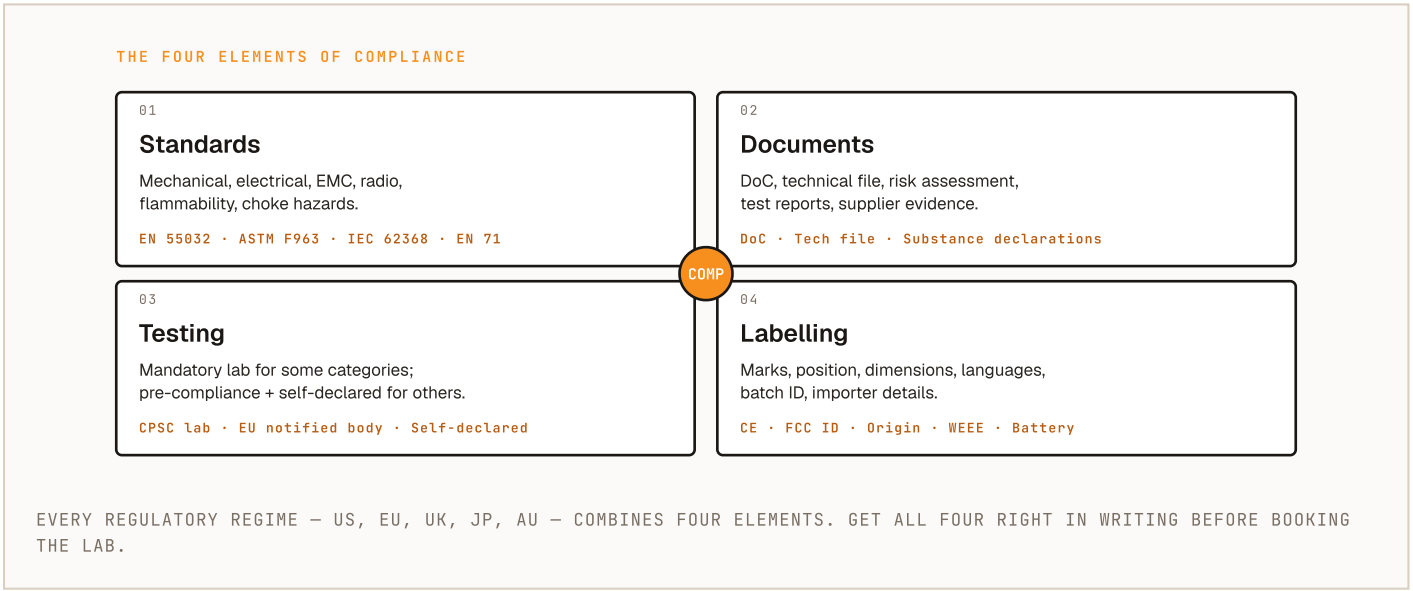
Reference for placing electronics on the US and EU markets — applicable rules, technical-file structure, pre-compliance workflow, lab cost benchmarks, and timeline from kickoff to certificate.

REVISION	ISSUED	OWNER	COMPANION
2.0	May 2026	Ideambox engineering	PDF reference

ABSTRACT

The importer (or local manufacturer) is legally responsible for placing a compliant product on the market. The supplier builds to the specification provided. This document maps the regulatory landscape for the US and EU, the contents of a defensible technical file, label and marking requirements, the four-step compliance workflow, lab cost benchmarks, and certification timelines.

Not a substitute for a Notified Body or regulatory consultant. This is the working reference an engineering team uses to scope compliance work, prepare a technical file, and verify supplier capability.



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1. Compliance fundamentals

Every regime combines standards, documents, testing, and labelling. The importer carries legal responsibility.

01	02	03	04
STANDARDS	DOCUMENTS	TESTING	LABELS
mechanical, EMC, radio, substances	DoC, technical file, evidence	mandatory lab or self-declared	CE, FCC, country, importer

1.1 Responsibility allocation

ROLE	LEGAL RESPONSIBILITY	DOCUMENTS OWNED
Importer / local mfr	All compliance for the market	Technical file, DoC, supplier evidence
Supplier	Build to provided spec	Manufacturing records, sub-supplier evidence
Notified Body	Conformity assessment (when required)	NB certificate
Authorised Representative (EU)	Hold tech file in EU; respond to surveillance	Same as importer
Distributor	Verify CE mark + DoC present	Records of due diligence

1.2 Why supplier "compliance" claims need verification

- **Suppliers in China and SE Asia are not tracking foreign regulations as their day job.**
- **"EU-compliant" without lab reports + supplier substance declarations + matched standards is not evidence.**
- **Verify with the issuing lab directly, not from a scan the supplier sends. Verification is free; lab phone numbers are on the certificate.**

2. US ↔ EU regulatory landscape

The two regimes overlap in concept but differ in mechanics. Map both before designing the technical file.

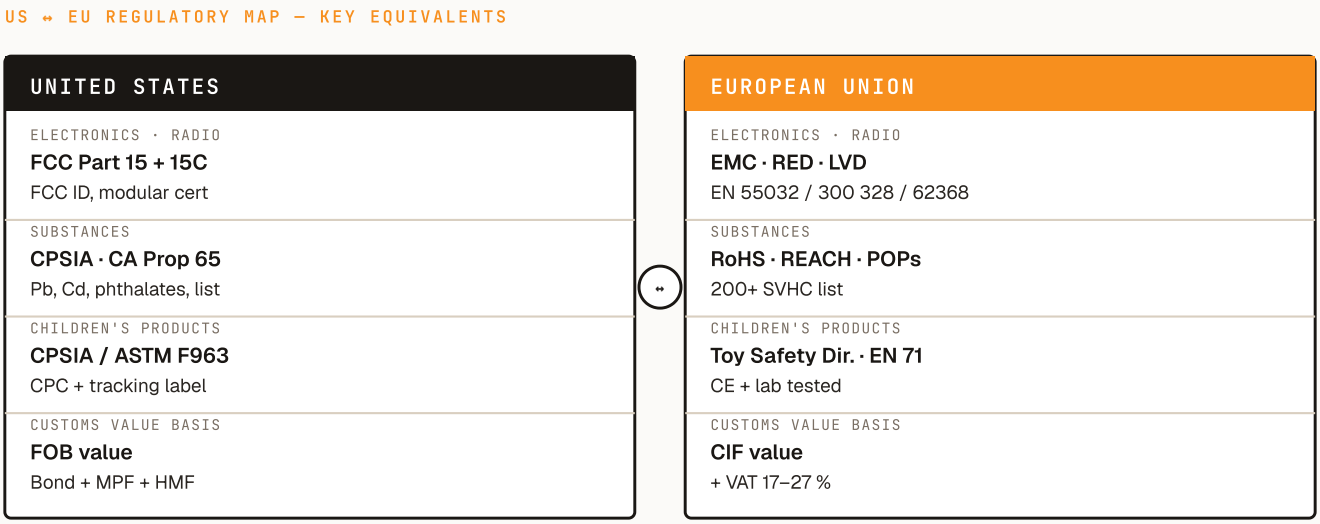

FIG 2.1 US ↔ EU REGULATORY MAP. SAME PRODUCT CATEGORY, DIFFERENT DIRECTIVES, STANDARDS, AND CUSTOMS-VALUE BASIS.

2.1 US regulatory stack

CATEGORY	REGULATION	KEY STANDARDS (CURRENT REVISION)	SELF-DECLARED
Children's products	CPSIA + 15 USC § 2063	ASTM F963-23, 16 CFR 1303	No — lab + CPC
Electronics (unintentional)	FCC Part 15B	ANSI C63.4, C63.10	Yes — DoC
Electronics (intentional)	FCC Part 15C	KDB 996369 (Wi-Fi/BLE)	No — FCC ID + lab
Consumer goods	CPSC + 15 USC § 2052	CPSIA, Prop 65 (CA)	Mostly yes
State substances	CA Prop 65	OEHHA list (~900 chemicals)	Self-declared + label
Food contact	21 CFR 175/177	FDA	Some yes, some pre-market
Energy efficiency	DOE 10 CFR 430	Test procedure per category	DOE filing
Apparel labeling	16 CFR Part 303	Fiber Products Identification Act	Self-declared

2.2 EU regulatory stack

CATEGORY	DIRECTIVE (CURRENT)	KEY STANDARDS	SELF-DECLARED
Electrical safety (50–1000 V)	LVD 2014/35/EU	EN 60950-1 / EN 62368-1 (2024)	Yes — most consumer
EMC	EMC 2014/30/EU	EN 55032:2015+A11 / EN 55035:2017+A11	Yes — most consumer
Radio (Wi-Fi / BLE)	RED 2014/53/EU	EN 300 328 V2.2.2 / EN 301 489 series	Module pre-cert OK
Toys	TSD 2009/48/EC	EN 71-1 / -2 / -3 (mech, fire, substances)	No — lab + NB sometimes
Substances (electronics)	RoHS 2011/65/EU	EN IEC 63000:2018 (technical doc)	Yes
Substances (chemicals)	REACH (EC) 1907/2006	Annex XVII restrictions + SVHC list	Yes
Persistent pollutants	POPs (EU) 2019/1021	Annex I restrictions	Yes
Batteries	Battery Reg (EU) 2023/1542	Carbon footprint, removability	Phased 2024–2027
Eco-design	Eco-design 2009/125/EC	Per-product implementing regs	Some yes
WEEE	WEEE 2012/19/EU	Per-country registration	Country-by-country
Packaging waste	PPWR 2025	Each member-state implementation	Self-declared + EPR fees

2.3 Other CE-area markets

Recognise CE

- **Switzerland (de facto)**
- **Norway, Iceland, Liechtenstein (EFTA)**
- **Turkey (CU agreement)**

Require own mark / dual-mark

- **UK**
  UKCA mark (CE recognised through 2027)
- **Australia**
  RCM (Regulatory Compliance Mark)
- **Japan**
  PSE (T mark for self-declared, D mark for type approval)
- **South Korea**
  KC mark
- **Mexico**
  NOM (per product category)
- **Brazil**
  Anatel (radio), INMETRO

WATCH OUT — IMPORTER DETAILS ON LABEL (EU 2025)

Importer details (name and EU address) became mandatory on most product labels in 2025 under the EU Market Surveillance Regulation (EU) 2019/1020. A label without them risks customs hold-up even when the product is otherwise compliant. Format: "Imported by [Company Name], [Street], [City], [Country]." Minimum legibility per (EU) 765/2008 Article 9.

3. Lab cost + timeline benchmarks

Real cost and time figures for booking a compliance lab. Vary by lab tier and product complexity.

3.1 Test cost benchmarks (USD, 2025)

TEST	STANDARD	MID-TIER LAB	TIER-1 LAB (TUV, UL, INTERTEK)
FCC Part 15B (unintentional radiator)	C63.4	$1 500–3 000	$3 000–5 000
FCC Part 15C (Wi-Fi/BLE module pre-cert)	KDB 996369	$4 000–8 000	$8 000–15 000
FCC Part 15C (custom radio + antenna)	KDB 996369	$8 000–15 000	$15 000–30 000
CE EMC (EN 55032 + 55035)	—	$2 000–4 000	$4 000–8 000
CE LVD / Safety (EN 62368)	—	$2 500–6 000	$6 000–12 000
CE RED (EN 300 328)	—	$3 000–6 000	$6 000–12 000
RoHS testing (per substance group)	EN IEC 63000	$200–400 / report	$400–800
REACH SVHC screen	—	$300–600	$600–1 200
Battery UN 38.3	—	$3 000–8 000	$8 000–15 000
CPSIA + ASTM F963 (toy)	full panel	$1 500–3 500	$3 500–7 000
Drop test IEC 60068-2-32	—	$500–1 500	$1 500–3 000

3.2 Realistic timeline (electronics, EU + US)

```
T-0 Spec lock, pre-compliance plan written T+2 Pre-compliance EMC scan at supplier (in-house lab) T+3 Iterate on EMC issues found T+5 Pre-production samples available T+6 Book formal lab (4-6 week queue typical) T+10 Lab testing (1-3 weeks) T+13 Report review, design changes if needed T+15 Re-test (if needed; +$1 000-3 000) T+17 Technical file complete + DoC signed T+18 First production batch can ship
```

Total: 17–20 weeks from spec lock to compliant production. Plan backwards from the ship date.

3.3 Lab selection criteria

- **Accreditation**
  ISO 17025 minimum; ILAC mutual recognition for cross-border acceptance.
- **Local presence in target market**
  Faster turnaround, language, fewer shipping concerns.
- **Same-lab capability**
  Doing EMC + safety + radio + RoHS in one lab cuts lead time 30 %.
- **Pre-test review**
  A lab that pre-reviews your file in 1–2 hours before booking saves the cost of obvious re-tests.
- **Reputation in your category**
  Look for client list + similar products tested.

4. Technical file

The deliverable. Lab reports without a structured file are not a compliance defence.

4.1 Required documents

#	DOCUMENT	WHAT IT IS
1	Product description + variants	All SKUs under this DoC
2	Applicable directives + regulations	Each named with citation
3	Harmonized standards considered	With year of publication
4	EU Declaration of Conformity (DoC)	Signed by authorised person
5	Risk assessment	ISO 12100 frame
6	Test reports	Accredited lab when required
7	User manual + safety instructions	All official languages of EEA destination
8	Labels + packaging	All printed marks, position, dimensions
9	Supplier substance declarations	RoHS, REACH per-part
10	Component traceability records	Lot codes, date codes

4.2 Supporting documents

- **Technical file index**
  One-page TOC. Auditors look here first.
- **QA procedure**
  How production units are verified against the file.
- **EU Authorised Representative**
  Required if manufacturer outside EU. Name, address, contract.
- **EORI number**
  Required for any commercial EU import.

4.3 Retention

- **Storage**
  Physical or digital archive accessible by the authorised person.
- **Retention period**
  10 years after last unit placed on EU market (most directives). 5 years for some.
- **Market surveillance readiness**
  File must be available within **10 days** of a national authority request.

5. Four-step workflow

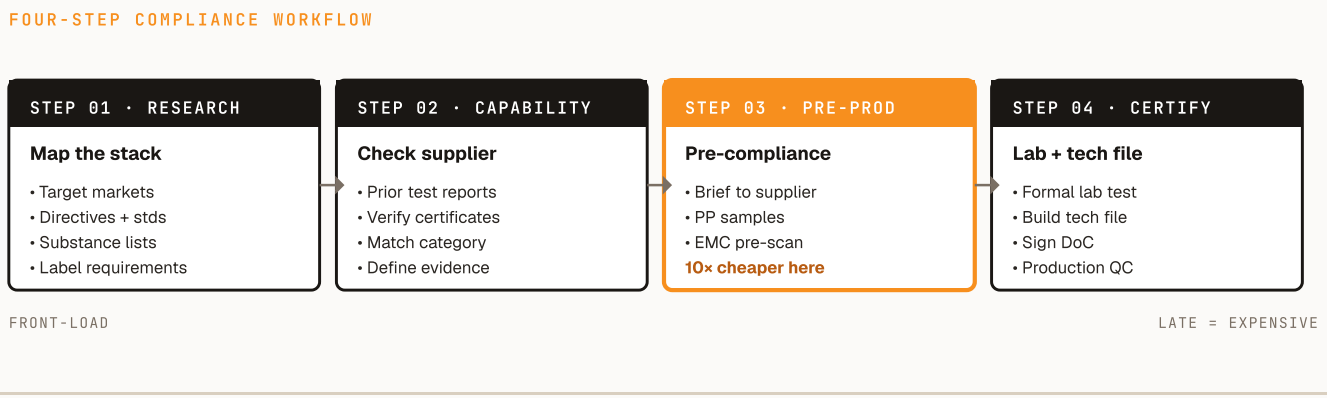

FIG 5.1 FOUR-STEP COMPLIANCE WORKFLOW. LATE CATCHES COST 10× TO 100× EARLY CATCHES. FRONT-LOAD THE DISCIPLINE.

5.1 Step 1 — Research (T-12 to T-10)

- **Identify target markets per first-year revenue plan.**
- **Map applicable directives. One product can hit 4–6 directives.**
- **Check substance lists current as-of date: RoHS, REACH SVHC (updated twice yearly), Prop 65 (updated quarterly), POPs.**
- **Check labelling: marks, positions, languages, minimum sizes.**
- **Check testing: mandatory lab, accredited lab, or self-declared.**

5.2 Step 2 — Supplier capability (T-10 to T-8)

- **Ask for evidence of prior compliance**
  Test reports, DoCs, CE-marked products. Verify with the issuing lab.
- **Match capability to product category**
  A supplier who's done LVD/EMC can do another; one who's done neither is starting from scratch.
- **Decide evidence interface**
  Which evidence the supplier provides (substance declarations); which you provide (lab tests).

5.3 Step 3 — Pre-production (T-8 to T-3)

- **Submit compliance brief to supplier**
  Specific standards, required reports, label files, packaging marks.
- **Pre-production samples from production line**
  Not the prototype bench.
- **Pre-compliance lab testing**
  EMC pre-scans (in-house or partner lab), safety review, substance screen. ~$300–800 per scan; catches 70 % of full-lab failures.

5.4 Step 4 — Certification + production QC (T-3 to T)

- **Formal lab test on production-line units.**
- **Build the technical file with version control.**
- **Sign the DoC**
  authorised person, dated, naming every directive and standard.
- **Establish production QC**
  verify production units against certified configuration.

- **Track field issues**
  Recalls, complaints, returns.

6. Common failures and remediation

Lab tests fail in predictable ways. Here's what to plan for.

6.1 EMC failures (top 5)

FAILURE	CAUSE	FIX	COST
Conducted emissions on USB power	Insufficient input filtering	Add CMC + bulk caps	$0.05–0.20/unit
Radiated emissions 30 MHz–1 GHz	Cable acting as antenna	Ferrite bead or shielded cable	$0.10–1.00/unit
Radiated emissions >1 GHz	PCB clock harmonics	Spread-spectrum, decouple	Firmware change
ESD failure on USB-C	No TVS diode	Add TVS array	$0.30–0.80/unit
Burst immunity on sensor input	Long unshielded sensor cable	Differential drive + filter	$0.15–0.50/unit

6.2 Safety failures (top 5)

FAILURE	CAUSE	FIX
Surface temp >70 °C (hand-held)	Thermal design	Heat sink, vent, derate
Battery thermal runaway	Cell quality or charger	Better cell, IC protection
Inadequate creepage on PSU	PCB layout	More spacing or insulation
Sharp edges (per test fingers)	Mechanical design	Re-design or deburr
Pinch point in moving parts	Mechanism	Guard, force limit, label

6.3 Label failures (top 3)

- **Missing importer details**
  2025 EU requirement; add to label.
- **CE mark below 5 mm height**
  Minimum height per (EU) 765/2008 Article 4.
- **Wrong country of origin format**
  Must be "Made in [Country]" or equivalent legibly.

> COST-BENEFIT OF PRE-COMPLIANCE
>
> Pre-compliance lab session: $500–2 000 typical. Full lab re-test after a failure: $3 000–8 000. Schedule slip from a failed lab: 4–8 weeks to re-test + redesign.
>
> ROI of pre-compliance: ~5–10× the cost, in saved re-test fees + ship date.

7. Engineering review checklist

Most failures are engineering choices, not paperwork. Walk through the design before booking the lab.

7.1 EMC + signal

- Star vs. mesh grounding documented
- Shield continuity verified
- Cable lengths minimised
- Openings <λ/4 above test frequency
- PCB return paths analysed
- Clock frequencies above limits identified

7.2 Safety + energy

- Surface temps measured at worst-case use
- Battery protection (charge, short, OT)
- Charging adapter / USB-PD compliant
- Sharp edges, pinch points designed out
- Test fingers per IEC 62368 simulated
- ESD protection on every accessible port

7.3 Supply-chain evidence

- RoHS / REACH declarations per part, per supplier, dated within 12 months.
- Component traceability (lot codes, date codes) confirmed with supplier.
- Production test plan documented: hi-pot, leakage, function, calibration.

> FINAL NOTE. CE marking is a self-declaration for most electronics. The manufacturer is on the hook, not the lab. The technical file protects the manufacturer in an audit. The file is only as good as the discipline that built it.