

Regulatory strategy built on certification experience

Four services that take an electronic product from regulatory uncertainty to market readiness, and keep it there.

WRITTEN FOR Electronics manufacturers · Importers

01 Compliance Gap Assessment

02 Turnkey Technical File

03 External Compliance Manager

04 Global Market Access

01

Compliance Gap Assessment

The regulatory map before the investment

THE PROBLEM IT SOLVES

Customs holds, marketplace delistings and authority requests usually happen because nobody worked out a conformity assessment strategy before launch.

WHAT IT INVOLVES

A fixed scope diagnostic covering the identification of applicable legislation (RED, CRA, EMC, LVD, RoHS, Machinery Regulation, CPR and others), the harmonised standards that apply, a review of the technical documentation that already exists, and a review of the CRA vulnerability reporting procedure. Every finding is ranked by criticality, so the corrective work can be sequenced by risk rather than by convenience.

What you get

DELIVERABLES

- Regulatory scope: applicable legislation and harmonised standards
- Documentary review of existing technical materials
- CRA Article 14 reporting readiness review
- Gap analysis with findings ranked by criticality
- Corrective action roadmap with cost and time estimates
- A strategy call to walk through the findings

WHEN TO ENGAGE

Before committing budget to testing, and whenever the regulatory status of a product is unclear.

FORMAT

Fixed fee. Delivered in five to seven working days.

02

Turnkey Technical File

From regulatory analysis to a signed Declaration of Conformity

THE PROBLEM IT SOLVES

The technical file is the record that demonstrates the product meets every applicable requirement. It is the foundation of the Declaration of Conformity, of the CE marking, and of the legal defence of the product if it is ever questioned. Building it means running laboratories, standards, documentation and risk analysis in parallel, which is where most schedules break.

WHAT IT INVOLVES

The full cycle through a single point of contact: regulatory analysis, harmonised standard selection, test strategy design with laboratory quotes and coordination, preparation of the technical file, development of the product risk analysis, and support after delivery. The service can optionally include the review of the production control plan, either to prepare the manufacturing line for certification audits or to meet the manufacturer's ongoing conformity obligations.

What you get

DELIVERABLES

- Test plan and laboratory coordination
- Complete technical file
- Product specific risk analysis
- EU Declaration of Conformity ready for signature
- Production control plan review when requested
- Post delivery support

WHEN TO ENGAGE

Once the design is defined and before any test campaign is booked.

FORMAT

Project based, scoped on product complexity.

03

External Compliance Manager

A regulatory expert without the headcount

THE PROBLEM IT SOLVES

Legislation is evolving, harmonised standards are being reviewed and market surveillance has intensified. Compliance is not finished once the CE marking is on the product, and exposure grows silently between one product launch and the next.

WHAT IT INVOLVES

A retained service giving direct and continuous access to senior regulatory expertise, without the cost or the complexity of an internal hire. It covers ongoing regulatory consultation, proactive tracking of normative changes affecting your products, regulatory review of new products and design variants, response to customs incidents and market surveillance actions, and the preparation of corrective action plans when certification audits of the manufacturing line result in findings.

What you get

DELIVERABLES

- A regulatory expert on call. Direct access, no juniors
- Technical support when incidents or inspections
- Impact analysis of product modifications and new variants
- Proactive tracking of normative and regulatory changes affecting your products
- Annual strategic review of the full product portfolio

WHEN TO ENGAGE

Once products are on the market and no one internally is tracking regulatory change.

FORMAT

Monthly retainer. Scope defined by portfolio size. No minimum commitment.

04

Global Market Access

One coordinated strategy for every target market

THE PROBLEM IT SOLVES

Most manufacturers certify market by market. New laboratories, a new set of tests and a new stack of documentation for each country, with work repeated that was already done for the EU file.

WHAT IT INVOLVES

A structured international compliance strategy built on the work already completed. It identifies testing equivalences, sequences certifications for cost efficiency, leverages the CB Scheme where applicable, and coordinates laboratories and certification bodies across regions through a single point of contact.

MARKETS COVERED

UNITED KINGDOM

UKCA

UNITED STATES & CANADA

FCC · UL · ISED

IECEE

CB Scheme

JAPAN

MIC

AUSTRALIA & NEW ZEALAND

RCM

SOUTH KOREA

KC Mark

Middle East, South Africa, India, Brazil, Mexico and other markets on request.

What you get

DELIVERABLES

- Certifications required for each target market
- Estimated cost per market
- Implementation timeline and certification sequence
- Identification of reusable test evidence and applicable equivalences
- Technical support throughout the process

WHEN TO ENGAGE

Before opening a new market, ideally while the EU technical file is still being built.

FORMAT

Scoped by number of target markets.

How this compares with the alternatives

TESTING LABORATORIES

They perform the measurements and their role ends there. They are not there to optimise the overall compliance strategy, and documentation issues that will later block a file rarely surface during a test campaign.

NOTIFIED BODIES

They evaluate conformity, they do not advise. A Notified Body cannot guide a manufacturer on how to meet a requirement. The boundary exists for good reason, and it leaves a gap.

GENERALIST CONSULTANCIES

They cover broad regulatory ground but rarely hold first hand experience of how a file is actually assessed, which is where most of the avoidable cost sits.

The manufacturer needs someone who knows the regulation, the evaluation process and the laboratory landscape well enough to build the strategy before the first test booking.

Where each service fits

REGULATORY SCOPE UNCLEAR

01 Compliance Gap Assessment

Before committing budget to testing.

SCOPE CLEAR, FILE NOT BUILT

02 Turnkey Technical File

Once the design is defined and before booking a test campaign.

PRODUCTS ALREADY ON THE MARKET

03 External Compliance Manager

When no one internally is tracking regulatory change.

EXPANDING BEYOND THE EU

04 Global Market Access

Before opening a new market.

START HERE

Every compliance project starts from a different position. Tell me where yours is and I will tell you what it needs.

Request a strategic call

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