

Guide to CE Marking

**Strategic guideline for technical compliance, laboratory testing,
and legally compliant labeling**

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Important Information for International Manufacturers, Importers, and Distributors

1. What is CE Marking and Why Does It Concern You?

The CE marking (Conformité Européenne) is not a voluntary quality, safety, or origin label, but a legally mandatory conformity mark of the European Union. By affixing the marking, a market participant legally declares that the product fully complies with all applicable harmonized European directives and regulations and has undergone all required conformity assessment procedures. It therefore functions as a legal “passport” for the European Single Market.

The fundamental principle of the EU Single Market:

Without valid CE marking, there is no legal market access—for all products falling under at least one CE directive.

Typical product categories include:

Electronics & Electrical Equipment:

Regulated by the Low Voltage Directive (LVD 2014/35/EU), EMC Directive (2014/30/EU), and Radio Equipment Directive (RED 2014/53/EU).

Machinery & Industrial Equipment:

Covered by the Machinery Directive (2006/42/EC) and the new Machinery Regulation (EU) 2023/1230.

Toys & Consumer Goods:

Governed by the Toy Safety Directive (2009/48/EC).

Medical Devices:

Subject to strict requirements under MDR (EU) 2017/745.

Construction Products:

Defined under the Construction Products Regulation (CPR (EU) No. 305/2011)

Reality for Non-EU Importers and Sellers

Many foreign manufacturers mistakenly believe that simply placing a CE logo on a product ensures compliance. In reality, the logo is only the visible result of a complex process involving technical validation, testing, and documentation. Without this process, the product is legally non-compliant—even if the CE mark appears correct.

2. Consequences of Non-Compliance

European market surveillance operates under strict regulatory frameworks and is becoming increasingly digitalized. Due to automated algorithms and systematic interfaces with major e-commerce platforms, the risk of detecting non-compliant products has increased exponentially. Violations trigger severe enforcement measures:

Sales bans and recalls:

Authorities impose immediate sales prohibitions. Products already sold must be actively recalled from end consumers at the expense of the distributor.

Automated marketplace bans:

Platforms such as Amazon, eBay, Allegro, or Temu irreversibly block listings (ASINs) and entire seller accounts if required compliance documents cannot be submitted digitally within a few days.

Customs blocks and destruction:

Border authorities stop shipments upon import. Without valid technical documentation or a correct Declaration of Conformity, imports are denied and goods are destroyed at the importer's expense.

Fines and criminal liability:

Significant fines in the five- to six-figure range may be imposed. In cases involving personal injury, responsible individuals and company directors may face criminal prosecution.

Particularly critical:

Incorrect, incomplete, misleading, or unjustified CE marking is treated exactly the same as having no CE marking at all under European administrative law and leads to identical severe consequences.

3. The 5 Core Requirements of CE Marking (What You Must Do)

To legally place a CE-required product on the EU market, the manufacturer or distributor must fully meet five fundamental obligations:

Identify applicable directives:

A precise analysis must determine which EU regulations apply. Often, multiple directives apply simultaneously (e.g., EMC, LVD, and RoHS for household appliances).

Conduct a systematic risk assessment:

All potential hazards (mechanical, electrical, thermal, chemical, electromagnetic) must be identified and minimized through design measures.

Prepare technical documentation:

This includes design drawings, bills of materials, circuit diagrams, software architectures, and proof of testing. Documentation must be retained for at least 10 years after the last product is placed on the market.

EU Declaration of Conformity (DoC):

An official legally binding document in which the manufacturer confirms compliance with all applicable directives and harmonized European standards (EN).

Affix CE marking correctly:

The CE logo must be visibly, legibly, and permanently affixed in the legally specified proportions on the product or packaging.

4. The Roadmap to CE Compliance: 4 Steps to Market Approval

As your technical and strategic compliance partner, we guide you through the entire conformity assessment process:

Step 1: Product category analysis

We identify all relevant EU directives and determine whether and to what extent CE marking is required.

Step 2: Risk assessment & testing strategy

We conduct hazard analysis and create a tailored laboratory testing roadmap based on harmonized EN standards.

Step 3: Documentation & Declaration of Conformity

We compile the technical file, verify supplier certificates, and prepare a legally compliant DoC for your signature.

Step 4: Labeling & market entry

We review product labeling, packaging, and instructions to ensure a smooth and compliant market launch.

5. Your Advantages with Our Professional Support

Secure market access:

No sudden, algorithmic account suspensions on Amazon or lengthy customs blockages at EU external borders.

Absolute legal certainty:

Full protection against competition law warnings from competitors and safeguarding against civil liability claims in case of damages.

Time and cost savings:

Avoidance of extremely costly development errors and incorrect duplicate testing in non-recognized laboratories outside the EU.

Holistic end-to-end service:

Technical engineering expertise combined with regulatory know-how from product development to after-sales audit.

6. Important Distinction: CE vs. GPSR, PPWR, EPR, ESPR & DPP

A fundamental mistake in modern compliance management is to view CE marking in isolation. The European Union has drastically modernized the legal framework for the Single Market. Today, CE marking is only one component within a multidimensional compliance architecture. The following provides the necessary functional differentiation:

6.1 CE Marking vs. GPSR (General Product Safety Regulation – (EU) 2023/988)

While CE marking applies only to product groups explicitly regulated by harmonized sector-specific directives, the GPSR functions as a comprehensive legal safety net for all non-food consumer products on the market.

Scope of application: CE applies sector-specifically; GPSR applies universally to all B2C goods (including those not subject to CE requirements, such as conventional furniture, clothing, jewelry, or hand tools).

Responsible person: The GPSR completely prohibits the sale of consumer products via distance selling (online trade) if no economic operator established in the EU (manufacturer, importer, or a formally appointed authorized representative) with a full postal address and digital contact details is indicated on the product, the packaging, or the online listing.

Important: A CE-compliant product is by no means automatically GPSR-compliant. The GPSR requires additional risk assessments specifically for e-commerce, as well as extended traceability and recall management processes.

6.2 Packaging Requirements: PPWR and EPR

These two regulations primarily do not relate to the technical function or inherent safety of the product itself, but rather to its packaging materials and their end-of-life lifecycle:

PPWR (Packaging and Packaging Waste Regulation):

This is a directly applicable EU regulation. It prescribes strict reduction targets for packaging volumes, bans certain single-use packaging types, and mandates classification into standardized recycling categories. Packaging must also be labeled with harmonized sorting pictograms across Europe.

EPR (Extended Producer Responsibility):

This is the underlying financial and organizational principle. Anyone who places packaged products, batteries, or electrical equipment on the market in an EU country is required to register in the respective target country with a national register (e.g., Stiftung EAR for WEEE/electronic waste or the LUCID packaging register in Germany) and pay system participation fees (recycling license fees). Without EPR registration numbers, online marketplaces automatically block listings.

6.3 The Future of Product Design: ESPR and the Digital Product Passport (DPP)

These instruments are transforming EU market access from a purely safety-based assessment into a comprehensive sustainability evaluation:

ESPR (Ecodesign for Sustainable Products Regulation):

The Ecodesign Regulation establishes the legal framework for designing products to be circular across their entire lifecycle. It sets requirements for durability, reparability, reusability, recycled content, and the reduction of the product's carbon footprint.

DPP (Digital Product Passport):

This is the digital implementation tool of the ESPR. Products falling under ESPR implementing measures (gradually introduced for textiles, batteries, consumer electronics, and metals) will be required to carry a machine-readable data carrier (e.g., a QR code or RFID chip). Through this passport, customs authorities, recyclers, and end users can directly access standardized data on material composition, supply chain, and reparability. In the future, the EU Declaration of Conformity (DoC) will become an integral part of this digital passport.

7. Product-Specific Laboratory Testing and Practical Examples

A CE marking may only be affixed once conformity has been demonstrated through objective test reports. The type of required testing depends precisely on the product category and the applicable standards.

Practical Example 1: Consumer Electronics (e.g., Bluetooth headphones with lithium-ion battery)

Applicable Directives & Standards: Radio Equipment Directive (RED 2014/53/EU), EMC Directive (2014/30/EU), RoHS Directive (2011/65/EU); EN 62368-1 (Safety), EN 300 328 (Radio).

Required Laboratory Tests:

- **EMC Testing:** Measurement of radiated emissions and testing of ESD immunity (electrostatic discharge).
- **Radio Testing:** Frequency band and transmission power measurements to prevent signal interference.
- **Electrical Safety:** Testing for overheating, short circuits, and battery safety (battery testing according to IEC 62133).
- **RoHS Screening:** Chemical laboratory analysis for restricted heavy metals (lead, cadmium) and plasticizers in materials.

Additional Obligations: GPSR responsible person, WEEE registration (EPR), battery registry notification, and future DPP requirements.

Practical Example 2: Mains-Powered Household Appliances (e.g., Electric Kettle, 230V)

Applicable Directives and Standards: Low Voltage Directive (LVD 2014/35/EU), EMC Directive (2014/30/EU), Ecodesign Directive (ErP); EN 60335-1 and EN 60335-2-15; Food Contact Compliance (LFGB / EC 1935/2004).

Required Laboratory Tests:

- **High voltage and insulation testing:** Verification of protection against electric shock.
- **Leakage current measurement:** Testing of protective conductor current under maximum thermal load.
- **Heating test:** Measurement of critical component temperatures during continuous operation to prevent fire hazards.
- **Dry-boil protection test:** Verification of automatic safety shut-off when operated without water.
- **Migration test:** Laboratory testing to determine whether chemical substances migrate from plastic materials into boiling water.

Additional Obligations: GPSR traceability, WEEE registration (Electrical Equipment Act), PPWR sorting instructions on packaging.

Practical Example 3: Children's Toys (e.g., Plush Toy with Integrated Sound Module)

Applicable Directives and Standards: European Toy Safety Directive (2009/48/EC), EMC Directive (for electronics); EN 71-1 (Mechanical Properties), EN 71-2 (Flammability), EN 71-3 (Migration of Certain Elements).

Required Laboratory Tests:

- **Tensile test:** Verification that small parts (e.g., plastic eyes or battery compartments) cannot detach and be swallowed.
- **Drop test:** Mechanical stress testing by dropping from a legally defined height onto a hard surface.
- **Flammability test:** Measurement of flame propagation speed in textile and plush materials.
- **Chemical analysis (EN 71-3):** Laboratory extraction tests for heavy metals, phthalates (plasticizers), and azo dyes.

Additional Obligations: Strict GPSR age labeling (e.g., “Not suitable for children under 3 years” warning symbol), EPR packaging licensing, and strict marketplace pre-compliance checks.

Practical Example 4: Industrial Machinery (e.g., Packaging Machine with Integrated Conveyor Belt)

Applicable Directives and Standards: Machinery Directive (2006/42/EC) and the new Machinery Regulation (EU) 2023/1230, EMC Directive (2014/30/EU); EN ISO 12100 (Risk Assessment), EN ISO 13849-1 (Functional Safety).

Required Laboratory Tests:

- **Functional safety testing:** Validation and calculation of the Performance Level (PL) for emergency stop switches, safety doors, and light curtains.
- **Protective conductor test:** Measurement of the continuity of the entire grounding system of the machine.
- **Noise emission measurement:** Instrument-based determination of the sound pressure level directly at the operator's workplace.
- **Stability test:** Analytical and physical verification of tipping stability under maximum dynamic load conditions.

Additional Obligations: Mandatory inclusion of a physical, printed operating manual, and compliance with the transition to the new Machinery Regulation.

8. CE Marking in E-Commerce

Stricter and increasingly automated monitoring mechanisms apply, particularly in e-commerce. Online marketplaces are legally co-responsible for the compliance of products offered on their platforms under European legislation (such as the Digital Services Act and the GPSR). Today, marketplaces carry out standardized and fully automated checks on:

- The CE relevance of a product based on stored customs tariff numbers (HS codes) and product classifications.
- The existence of a plausible, up-to-date, and formally correct EU Declaration of Conformity (DoC).
- The complete digital identification of the manufacturer as well as the EU responsible person directly within the online listing.

The incalculable risk for sellers: Products can be algorithmically delisted suddenly and without warning, even after months of successful sales, as soon as a spot check by market surveillance authorities or a complaint from a competitor is triggered. The immediate consequences include significant revenue losses, blocked inventory (e.g., in Amazon FBA warehouses), costly return logistics, and even the complete and permanent suspension of the seller's entire account.

9. Your Liability as a Manufacturer or Distributor

An aspect that is often fatally underestimated in practice is the legal equivalence of economic operators under European product safety law. Many distributors operate under a false sense of security because they merely import goods, purchase them as **white-label** products, or sell them via **dropshipping**. However, EU law draws a clear and unambiguous line:

Legal manufacturer status:

As soon as you import products from a non-EU country (e.g., China, USA) into the European internal market, register white-label products under your own brand, or act as the first contractual partner established in the EU within a dropshipping model, you are legally considered the manufacturer.

As a consequence, you bear full and unlimited liability with your company (and in the worst case, personally as a managing director) for: the product-specific safety of end consumers, the formal and material conformity of the goods, the availability of technical documentation, as well as for any material damage, personal injury, and financial losses caused to end users by defective or unsafe products.

10. Why Many CE Projects Fail

Experience shows that compliance projects rarely fail due to the complexity of the technical measurements themselves, but primarily because of structural and organizational errors:

Unclear responsibilities: There is no dedicated person within the company managing the compliance process; procurement, product development, sales, and quality management operate in isolation.

False assumptions (“the supplier has taken care of it”): International traders rely unchecked on documents provided by manufacturers. In over 80 percent of cases, these “certificates” (often falsified or incomplete test reports from non-accredited or fake laboratories) are completely worthless in front of European authorities.

Lack of a structured approach: Testing is only initiated after production is completed, resulting in extremely costly rework or total product rejection.

Missing integration with GPSR and PPWR: The product may be technically compliant, but due to formal labeling errors (e.g., missing address of the responsible person, missing packaging labels), it is still not legally marketable and will be blocked.

11. Our Approach: Holistic EU Compliance

We do not view CE marking as an isolated bureaucratic hurdle, but rather manage your product compliance through an integrated overall system.

Our methodological approach combines the three decisive pillars of modern market compliance:

[**CE Marking** (Technical Safety)] + [**GPSR** (Consumer Protection and Traceability)] + [**PPWR** and **EPR** (Environment and Circular Economy)]

The result for your company: A fully legally compliant, predictable, and scalable market access across the entire European Union—without time-consuming duplicate processes, costly delays at customs, or the risk of subsequent product modifications.

12. Mandatory CE Labeling Requirements for Product and Packaging

Market surveillance authorities assess labeling based on a strictly predefined legal hierarchy:

Everything that physically fits on the product **MUST** be placed directly on it. Relocating mandatory information to the packaging or the user manual is only legally permitted if the product is demonstrably too small (e.g., microelectronics) or if the surface characteristics make permanent marking technically impossible.

Overview of mandatory elements:

CE Marking (Logo):

Must comply with exact legal proportions (the geometry of the two circles forming the “C” and “E” is precisely defined). A strict minimum height of 5 mm applies. The marking must be permanently affixed, resistant to wiping and scratching, and clearly visible.

Manufacturer Information:

Mandatory indication of the official company name (including registered legal form) and a complete, serviceable postal address (street, number, postal code, city, country). Providing only a website URL or an email address is legally insufficient and constitutes a formal violation.

Product Identification:

Each product must allow clear identification. This is ensured through mandatory specification of a model designation, type number, or a specific item number.

Traceability:

To enable precise identification of potential series defects in the event of a product recall, at least one of the following elements must be present: a serial number, a batch number, or a production batch ID.

EU Authorized Representative / Responsible Person:

If the manufacturer is located outside the European Union, the indication of the EU economic operator (Authorized Representative or responsible person under GPSR), including name and full postal address, is mandatory on the product or its packaging.

Safety and Warning Information:

If relevant for the safe use of the product, specific warning texts (e.g., “Warning! Not suitable for children under 3 years”) or standardized hazard symbols must be affixed.

Technical Specifications:

Depending on the applicable directive, specific performance data must be indicated (e.g., operating voltage in volts, power consumption in watts, frequency in Hz for electronics; maximum operating pressure for pneumatic components; net weight; year of manufacture).

Order of placement priority:

Priority 1: Directly on the product → **Priority 2:** On the sales packaging → **Priority 3:** In the instruction manual

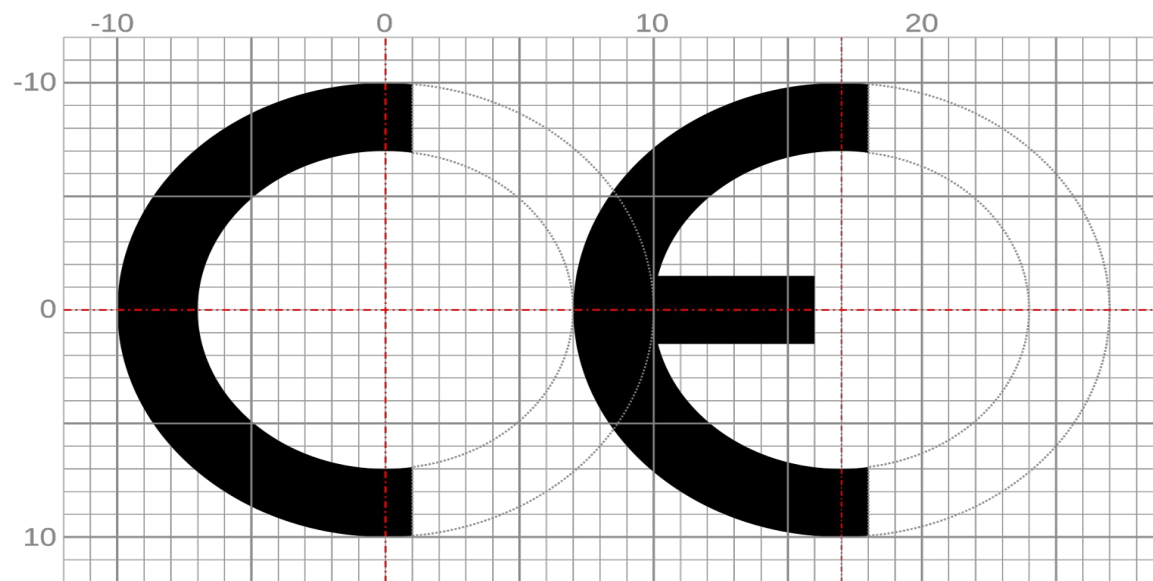
✗ Common Mistakes (very important)

- CE marking too small or incorrect
- Incomplete address information
- No serial/batch/lot number
- Product not clearly identifiable
- Information only on packaging (even though space on the product exists)
- Missing EU authorised representative (for non-EU manufacturers)

✓ Compact CE Checklist

A CE-compliant label includes:

- CE marking
- Manufacturer (name + address)
- Product identification
- Serial / batch / lot number
- EU authorised representative (if applicable)
- Warning and technical information (if applicable)



Compliant Display of the CE Marking

13. Checklist – Required Documents for the CE Pre-Audit

To ensure the regulatory maturity of your products can be assessed in a legally compliant manner, the documentation must be collected in a structured way. Please submit these documents in a single package (one separate email per product line) to

info@systemic-standards.com

Product & Basic Data

Product name, exact model designation; comprehensive product description including the defined intended use; technical functional description; list of target EU countries; and documentation of all model variants or planned product series.

Economic Operators

Full name and address of the manufacturer; if applicable: master data of the EU importer as well as the appointment certificate and address details of the Authorized Representative within the EU.

Technical Documentation

Technical design drawings, exploded views; complete bill of materials (BOM); electrical schematics, PCB layouts (for electronics); functional system descriptions; and specifications of integrated firmware or software versions.

Directives & Standards

Structured list of all applicable EU directives for the product (e.g., LVD, EMC, RoHS, RED, Machinery Directive); tabular overview of applied harmonized European EN standards; and documentation of the selected conformity strategy.

Test Reports & Laboratory Evidence

Complete EMC test reports; reports on electrical and mechanical safety; accredited test evidence for material and chemical compliance (RoHS test reports, REACH compliance evidence); official certificates or laboratory reports from Notified Bodies, where required.

Risk Analysis & Safety

Comprehensive risk assessment (e.g., hazard analysis according to EN ISO 12100 for machinery products); documentation of all implemented risk mitigation measures; technical safety concept; and a clear list of residual risks and required warnings.

Marking & Labeling

High-resolution photos or scale-accurate print layouts of the product labels / rating plate; documentation of the exact placement of the CE marking on the product; design drafts of the sales packaging including all mandatory information and PPWR sorting instructions.

User Manual / Instructions for Use

Complete operating instructions in all official languages of the EU countries where the product is intended to be sold; manufacturer-provided assembly and installation instructions; maintenance, servicing, and cleaning guidelines; as well as integrated, standards-compliant safety symbols.

Production Quality

Information and certificates relating to the production sites used; documentation of implemented quality management processes (e.g., ISO 9001 certificate of the manufacturing facility); evidence ensuring product conformity during ongoing mass production.

Sales / Distribution Information

Overview of primary sales countries within the EU; distribution channels used (e.g., Amazon FBA, own online shop, B2B specialist retail); current market entry status (entirely new product or review of an already market-available product).

Change History

Complete documentation of product changes (engineering change notes relating to design, electronic components, housing materials, or software revision states); evidence of supplier changes for critical components.

Optional Evidence

Additional internal quality guidelines; high-resolution factory or assembly photos of the product in an open state; existing CE documentation or declarations of conformity from technically similar predecessor products.

Liability & Insurance Proof

Formal evidence of active product liability insurance with territorial coverage for the entire EU. A minimum coverage amount of €1,000,000 is mandatory; due to the complex obligations under ESPR and GPSR, €2,000,000 to €3,000,000 is strongly recommended.

14. Next Step Toward Legally Compliant Market Approval

The European market offers excellent revenue opportunities, but it does not tolerate any negligence in regulatory compliance. Correcting shipments that have been blocked at customs after the fact, or lifting an official marketplace suspension, is in practice many times more expensive, time-consuming, and risky than a clean and structured initial implementation before the actual start of distribution.

Why Systemic Standards?

We do not believe in rigid bureaucracy, but in smart, systemic processes. We link deep legal and technical expertise with practical, economically sensible solutions for modern importers, manufacturers, and distributors. Whether it is a consumer good, complex electronics, or an industrial machine – we ensure that your products meet European safety standards not just on paper, but in actual daily practice.

Systemic Standards – Competence in Product Safety. Excellence in Compliance.

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