

CE Marking Readiness Checklist

This checklist is designed to help manufacturers, importers, and compliance professionals determine whether a product is ready for CE marking before it is placed on the European market.

CE marking is a legal declaration of conformity with applicable EU legislation. Before affixing the CE mark, all technical, regulatory, and documentation requirements must be fulfilled.

Use this checklist as a **pre-assessment tool** to verify readiness and identify any gaps that must be addressed.

Product Scope & Legal Applicability

- ☐ The product is covered by one or more EU harmonisation directives or regulations
- ☐ All applicable EU directives and regulations have been correctly identified
- ☐ The product is not excluded from CE marking requirements
- ☐ The intended use and foreseeable misuse have been clearly defined

Conformity Assessment Route

- ☐ The correct conformity assessment procedure has been determined
- ☐ It has been verified whether self-assessment is permitted
- ☐ It has been confirmed whether involvement of a Notified Body is required
- ☐ The selected conformity route complies with EU legal requirements

Standards & Technical Requirements

- ☐ Applicable harmonised EN standards have been identified
- ☐ Latest versions of standards have been used
- ☐ Deviations from harmonised standards (if any) are technically justified
- ☐ Essential health and safety requirements have been addressed

Risk Assessment & Testing

- ☐ A documented risk assessment has been completed
 - ☐ All identified risks have been reduced to an acceptable level
 - ☐ Product testing has been performed where required
 - ☐ Accredited laboratories have been used when mandated by legislation
 - ☐ Test results demonstrate compliance with applicable standards
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Technical Documentation

- ☐ Product description and specifications are complete
 - ☐ Design drawings and manufacturing information are available
 - ☐ Risk assessment documentation is included
 - ☐ Test reports and certificates are compiled
 - ☐ Applied standards are listed
 - ☐ User instructions and safety information are prepared
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Declaration of Conformity

- ☐ EU Declaration of Conformity has been drafted
 - ☐ All applicable directives and standards are correctly referenced
 - ☐ Manufacturer or authorized representative details are included
 - ☐ Declaration has been signed by a responsible person
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CE Marking & Labeling

- ☐ CE marking is affixed correctly and visibly
 - ☐ CE marking follows size and visibility requirements
 - ☐ Product labeling complies with EU legislation
 - ☐ Identification and traceability information is included
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Market Placement & Post-Market Obligations

- ☐ Product is ready to be placed on the EU market
- ☐ Technical documentation is retained for at least 10 years
- ☐ Procedures for post-market surveillance are in place
- ☐ Corrective actions can be taken if non-compliance is identified

Important Notice

This checklist is provided for informational purposes only and does not replace legal advice or conformity assessment performed by accredited bodies or authorities.

Responsibility for CE marking compliance remains with the manufacturer or the responsible economic operator.