CE Documentation Starter Checklist

A practical five-page orientation for machinery manufacturers and system integrators

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What this checklist does

This short guide helps you organise the work and recognise the main documentation categories before machinery is placed on the EU/EEA market or put into service. It is an orientation—not a complete conformity assessment for a particular machine.

Important timing note

As of this edition, Directive 2006/42/EC remains the principal EU machinery framework. Regulation (EU) 2023/1230 is scheduled to apply from 20 January 2027. Projects crossing that date should identify which requirements apply and plan the transition early.

Use it to	This checklist does not
• define the machine, its boundaries and intended use • identify responsibilities and applicable requirements • create a traceable technical-documentation structure • check whether key evidence exists before signing the declaration	• certify or approve a machine • select legislation or standards for your specific product • replace risk assessment, engineering validation, testing or legal advice • guarantee conformity or a legal outcome

Responsibility

The manufacturer remains responsible for the conformity assessment, technical documentation, declaration and correct use of CE marking.

The eight-step roadmap

Use this sequence as a project map. Some activities overlap and must be revisited when the design changes.

1. Define the product and responsible party	Describe the machine, intended use, reasonably foreseeable misuse, lifecycle and interfaces. Confirm who is acting as manufacturer and who may sign the declaration.
2. Identify applicable requirements	Determine which EU product rules apply to the machine and whether other legislation also applies. Record the reasoning; do not begin with a CE label.
3. Plan conformity assessment	Identify the applicable assessment route, responsibilities, required competence and whether third-party involvement is legally required.
4. Assess and reduce risks	Perform a documented risk assessment across the lifecycle. Apply the hierarchy of risk reduction and record decisions, residual risks and verification evidence.
5. Design and verify	Translate requirements and risk-reduction measures into design controls. Verify safety-related measures, calculations, tests and interfaces using competent methods.
6. Build the technical documentation	Maintain an indexed set of drawings, calculations, risk records, test results, component evidence, instructions and other required information.
7. Prepare instructions and declaration	Make instructions consistent with the actual machine and residual risks. Complete and sign the correct declaration only after the assessment is complete.
8. Apply CE marking and retain records	Apply CE marking only when justified. Preserve required records and control changes, variants, software updates and later modifications.

Technical-documentation starter list

The exact content depends on the product and applicable legislation. Mark each item: Available / In progress / Not applicable / Missing.

Identity and scope	□ Manufacturer and authorised-representative details, where relevant □ Machine designation, model, serial/variant identification □ Intended use, limits, lifecycle and foreseeable misuse □ Responsibility and approval matrix
Design and risk evidence	□ General description and technical-file index □ Overall and detailed drawings, schematics and explanations □ Risk assessment and documented risk-reduction decisions □ Calculations, test reports and verification/validation records □ Safety-function evidence where relevant
Requirements and external evidence	□ Applicable-legislation assessment and rationale □ List of applied standards or other technical specifications □ Supplier/component declarations and instructions □ Evidence for partly completed machinery, where relevant
User and release information	□ Instructions in required language(s) □ Installation, operation, maintenance and decommissioning information □ Residual-risk warnings and required protective measures □ Declaration draft and signatory authority □ Marking/nameplate information and traceability records

Release-readiness check

Do not treat this as a tick-box substitute for technical judgement. Each answer should be supported by identifiable evidence.

- □ Is the product definition stable, including variants, attachments and interfaces?
- □ Are the responsible manufacturer and authorised signatory clear?
- □ Is the applicable-legislation assessment documented and current?
- □ Does the risk assessment cover intended use, foreseeable misuse and lifecycle phases?
- □ Can each important risk-reduction measure be traced to design evidence or instructions?
- □ Have relevant safety measures, calculations and tests been verified by competent people?
- □ Are drawings, software/configuration references and component evidence aligned with the released machine?
- □ Do instructions reflect the actual machine, residual risks and required user measures?
- □ Are declaration references, product identity and applied standards consistent across documents?
- □ Is CE marking applied only after the required assessment and declaration are complete?
- □ Is there a controlled process for retention, revisions, variants and post-release changes?

Pause before release if

important evidence is missing; documents contradict each other; the machine differs from the reviewed design; safety measures are unverified; or responsibility for the declaration is unclear.

Common gaps and sensible next steps

Common documentation gaps

- The machine boundary or intended use is vague.
- Risk controls cannot be traced into drawings, verification or instructions.
- Supplier declarations are collected but not assessed for relevance.
- The standards list, declaration and technical documentation disagree.
- Instructions are generic or do not match the delivered configuration.
- Changes are made after assessment without documented review.

Your next 30 minutes

- Name one responsible owner for the documentation package.
- Create a document index with owner, revision, status and evidence link.
- Choose the three highest-risk or most uncertain gaps.
- Assign a next action and evidence requirement for each gap.
- Do not sign the declaration or apply CE marking merely because a deadline is approaching.

Official starting sources

European Commission — Machinery sector overview: https://single-market-economy.ec.europa.eu/sectors/mechanical-engineering/machinery_en

Directive 2006/42/EC on machinery — CELEX 32006L0042: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006L0042

Regulation (EU) 2023/1230 on machinery — CELEX 32023R1230: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32023R1230

Your Europe — Conformity assessment: https://europa.eu/youreurope/business/product-rules-compliance/general-product-compliance/conformity-assessment/index_en.htm

Need a structured second look?

ConformityDesk offers an asynchronous, fixed-scope review of existing machinery documentation. Request a free initial scope check at info@conformitydesk.com.