How to Create a Declaration of Conformity (DoC)

A strategic guide for manufacturers, importers and product compliance teams

Prepared by	Regulatory Strategy Consulting Kunz | Dr. Erika Kunz
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Scope	EU Declaration of Conformity governance, technical file readiness, evidence architecture and operating model
Audience	Manufacturers, importers, authorised representatives, brand owners, regulatory affairs, quality, product stewardship, sustainability, procurement and legal teams

Core thesis

A Declaration of Conformity is not the start of compliance. It is the formal output of a controlled evidence system. The document is only as strong as the applicability assessment, technical file, supplier evidence and governance process behind it.

Legal note: This white paper provides general regulatory information and strategic orientation. It does not constitute legal advice. Requirements vary depending on the legal framework, product category, market role and applicable EU or national legislation.

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1. Executive Summary

For many companies, the Declaration of Conformity is treated as the last administrative step before a product is placed on the market. This is a risky interpretation.

In reality, the Declaration of Conformity is one of the most important legal outputs of a product compliance system. It confirms that the responsible economic operator has identified applicable requirements, assessed conformity, collected evidence and formally accepts responsibility for compliance.

A weak Declaration of Conformity creates regulatory, commercial and liability risk. A robust DoC demonstrates that compliance has been managed systematically and can be defended to authorities, customers and auditors.

> **Executive insight**
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> The challenge is not creating a declaration template. The challenge is ensuring that every statement in the declaration is supported by traceable, current and defensible evidence.

2. Why the Declaration of Conformity Matters

Across many European regulatory regimes, the Declaration of Conformity acts as the formal statement through which a manufacturer or responsible economic operator confirms compliance with applicable legal requirements.

- CE-marked products
- Packaging under PPWR
- Batteries
- Machinery and electrical equipment
- Radio equipment
- Construction products
- Product groups that may be covered by future ESPR delegated acts

The DoC is therefore the bridge between regulatory requirements and technical evidence. Without supporting documentation, it is only a signed statement. With appropriate documentation, it becomes one of the strongest compliance tools available to a company.

3. What a DoC Is and What It Is Not

A DoC is	A DoC is not
A formal legal statement by the responsible economic operator.	A laboratory test report.
The conclusion of a conformity assessment process.	A supplier declaration.
A controlled document linked to a technical file.	A substitute for technical documentation.
A document that identifies applicable legislation and standards.	A generic certificate that proves all compliance questions.
A sign-off that should be supported by evidence and governance.	A template exercise performed at the end of a project.

4. The Biggest Mistake Companies Make

Many organizations begin by asking what the Declaration of Conformity template should look like. This is usually the wrong first question.

> **Better question**
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> Do we have sufficient evidence to support every statement in the Declaration of Conformity?

Authorities and customers may review formatting, but the more important question is whether the organization can prove the claims made in the document. A well-designed declaration supported by weak evidence creates risk. A simple declaration supported by strong evidence is typically much stronger.

5. Step-by-Step Process

Step	Objective	Key questions	Output
1. Determine responsibility	Identify the legal entity or economic operator responsible for the DoC.	Who is the manufacturer, importer, authorised representative or brand owner?	Role and responsibility map.
2. Identify applicable legislation	Determine which EU and national requirements apply.	Is the product, packaging or component in scope of one or more frameworks?	Regulatory applicability assessment.
3. Define standards and specifications	Select the route to demonstrate conformity.	Which harmonised standards, specifications or test methods are used?	Standards and requirements matrix.
4. Build the evidence base	Collect and validate supporting documentation.	Can every claim in the DoC be traced to evidence?	Technical file and evidence index.
5. Draft the DoC	Prepare a clear, controlled declaration.	Does the declaration identify product, legislation, standards, entity, signatory and date?	Signed DoC.
6. Maintain and update	Keep the declaration valid through product and legal changes.	What triggers review or re-issue?	Change-control process.

5.1 Determine Who Is Responsible

Responsibility must be clarified before drafting. Depending on the framework, responsibility may sit with the manufacturer, importer, authorised representative, private-label owner or another defined economic operator. This is particularly important for contract manufacturing, OEM arrangements, private labels and global supply chains.

5.2 Identify Applicable Legislation

A DoC can only reference legislation that actually applies. The quality of the declaration depends directly on the quality of the regulatory applicability assessment. Companies should document why a framework is applicable, or why it is not applicable.

5.3 Define Applicable Standards and Specifications

Many regulations contain high-level essential requirements. Harmonised standards, international standards, technical specifications and internal validation protocols often provide the practical route for proving conformity.

5.4 Build the Evidence Base

Every statement in the DoC should be traceable to a supporting record. This includes product specifications, risk assessments, test reports, design records, supplier declarations, certificates, recyclability evidence and sustainability evidence where relevant.

5.5 Draft and Approve the Declaration

The declaration should be understandable to regulators, customers and auditors. It should be signed by an authorised person and controlled through a document-management process.

5.6 Maintain the Declaration

A DoC should not be static. It must be reviewed when products, suppliers, materials, legislation, standards or intended uses change.

6. Required Evidence and Technical File Architecture

The DoC should be the visible output of a broader evidence architecture. The following structure can be adapted to product-specific frameworks such as PPWR, batteries, machinery, electronics, construction products or future ESPR product groups.

Evidence layer	Typical content	Typical owner
Product identification	Product name, model, part number, SKU, version, intended use and market.	Product management / regulatory
Regulatory applicability	Applicable regulations, directives, delegated acts, implementing acts and exclusions.	Regulatory affairs / legal
Technical assessment	Risk assessments, design records, calculations, test plans, performance data and validation reports.	R&D / engineering / quality
Supplier evidence	Material declarations, substance declarations, certificates, recycled-content evidence and contractual warranties.	Procurement / supplier quality
Compliance evidence	Test reports, notified-body documentation where relevant, conformity assessment records and standards matrix.	Quality / regulatory
Sustainability and circularity evidence	LCA, PCF, recyclability assessment, substances-of-concern data and DPP-related data where relevant.	Sustainability / product stewardship
Approval and change control	Sign-off, version control, review triggers, audit trail and re-issue history.	Quality / document control

7. Why Supplier Declarations Are Not Enough

Supplier declarations are important, but they do not automatically transfer legal responsibility. The organization issuing the DoC remains responsible for the claims made in the declaration.

This is particularly relevant for substances of concern, PFAS, recycled content, ESG claims, product carbon footprints, packaging recyclability, critical raw materials and Digital Product Passport information.

Risk-based principle

Supplier information should be validated according to risk. High-risk materials, products, suppliers or claims may require additional evidence, testing, certificates, audits or contractual warranties.

8. DoCs Under ESPR, PPWR and DPP

Traditional Declarations of Conformity often focused on safety, technical performance or CE-marking requirements. Future product and packaging regulations increasingly require evidence that covers sustainability, circularity and data transparency.

- ESPR may introduce performance and information requirements for product groups, including substances of concern, durability, repairability, recyclability and environmental footprint.
- PPWR creates new packaging-related evidence needs, including recyclability, recycled content, minimisation, labelling and substance restrictions.
- Digital Product Passport requirements may connect conformity evidence with structured, machine-readable product data.

This means that future DoC processes will increasingly depend on broader datasets and stronger data governance than traditional compliance programs.

9. What Authorities and Auditors Typically Look For

Question	What strong evidence looks like	Weakness indicator
Does the company understand its obligations?	Documented applicability assessment and regulatory matrix.	Legislation added to templates without clear rationale.
Is there supporting evidence?	Technical file with traceable reports and supplier records.	Declarations signed without evidence index.
Is responsibility clearly assigned?	Named legal entity, signatory and approval workflow.	Unclear manufacturer/importer/brand-owner role.
Is the process repeatable?	Controlled template, change triggers and training.	One-off declarations created manually by individuals.
Is the declaration current?	Version control and review after product or legal changes.	Old references to withdrawn standards or outdated legislation.

10. Creating a DoC Operating Model

The strongest organizations treat DoCs as a controlled business process, not a document template. A mature operating model connects regulatory interpretation, technical validation, supplier evidence, quality control and management accountability.

Function	Typical role	Control point
Regulatory affairs	Legal interpretation and applicability assessment.	Regulatory matrix approval.
Engineering / R&D	Design data, product specifications and technical validation.	Technical evidence approval.
Quality	Document control, records and conformity assessment process.	Version control and release process.
Procurement	Supplier declarations, certificates and contractual evidence.	Supplier evidence validation.
Sustainability	Environmental and circularity evidence where relevant.	Claims and methodology review.
Legal	Liability, role mapping and signatory authority.	Legal entity and responsibility review.
Management	Accountability and resource allocation.	Executive sponsorship and escalation.

11. Practical DoC Checklist

- Confirm the responsible legal entity and market role.
- Identify all applicable regulations, directives and product-specific requirements.
- Document applicable standards, specifications and conformity routes.
- Create an evidence index linked to the technical file.
- Validate supplier evidence using a risk-based approach.
- Confirm that product identification is precise and unambiguous.
- Ensure the DoC is signed by an authorized person.
- Create document control, version history and review triggers.
- Review the DoC whenever legislation, standards, supplier data, product design or intended use changes.
- Align the DoC process with PPWR, ESPR and DPP data requirements where relevant.

12. Outlook and Conclusion

A Declaration of Conformity should never be treated as an administrative formality. It is the visible output of a company's compliance system.

If the evidence behind the declaration is weak, the declaration is weak. If the evidence is robust, controlled and traceable, the declaration becomes one of the strongest demonstrations of regulatory maturity available to an organization.

Final message

The best Declarations of Conformity are not created by templates. They are created by disciplined compliance governance.

References

[1] European Commission Blue Guide on the implementation of EU product rules, as applicable to CE marking and conformity assessment frameworks.

[2] Regulation (EU) 2025/40 on packaging and packaging waste, for packaging conformity and technical documentation requirements.

[3] Regulation (EU) 2024/1781 establishing a framework for ecodesign requirements for sustainable products.

[4] European Commission Digital Product Passport information, for future structured product information requirements.

About Regulatory Strategy Consulting Kunz

Regulatory Strategy Consulting Kunz supports organizations in navigating complex regulatory landscapes and transforming compliance into a source of strategic value. The practice provides independent strategic advice, expert assessments and project-based support for organizations facing regulatory change, sustainability transformation and complex compliance challenges.

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