



Technical Documentation Requirements Checklist



Technical Documentation

Manufacturers shall draw up technical documentation regarding the products they place on the market, which should contain the necessary information to prove that those products are safe. The technical documentation should be based on an internal risk analysis carried out by the manufacturer.

The amount of information to be provided in the technical documentation shall be proportionate to the complexity of the product and the possible risks identified by the manufacturer. In particular, manufacturers shall provide a general description of the product and the elements necessary to assess its safety. In the case of complex products or products presenting possible risks, the information to be provided might need a more extensive description of the product. In such cases, an analysis of those risks and the technical means adopted to mitigate or eliminate the risks should also be included.

Where the product complies with European standards or other elements applied to meet the general safety requirement laid down in the General Product Safety Regulation (GPSR), the list of the relevant European standards or the other elements should also be indicated.

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Requirements Checklist

To ensure full compliance with the GPSR, businesses shall maintain at least the following documentation:

- A general description of the product and its essential characteristics relevant for assessing its safety.
- Risk Assessment: Detailed assessment identifying potential hazards associated with the product and the steps taken to mitigate these risks.
- Traceability information: The address of the economic operator.

Depending on the complexity of the product and the possible risks identified by the manufacturer, the technical documentation could also include:

- Test Results: Records of all safety tests conducted on the product, including results from stress tests, usability tests, and any other relevant assessments.
- Technical Files: Comprehensive technical documentation, including design specifications, materials used, and construction methods.
- Compliance Statements: If relevant, declarations of conformity with relevant safety standards and regulations, such as CE marking where applicable.
- Supply Chain Documentation: Records of the supply chain, including details of manufacturers, importers, and any EU-based economic operators.
- Corrective Action Records: Documentation of any corrective actions taken, such as product recalls or modifications, including communication with authorities and consumers.
- Product Information: Labels, user manuals, and safety instructions provided with the product, ensuring they meet regulatory requirements.
- Market Surveillance Correspondence: Any communication with market surveillance authorities, including requests for information and responses provided.