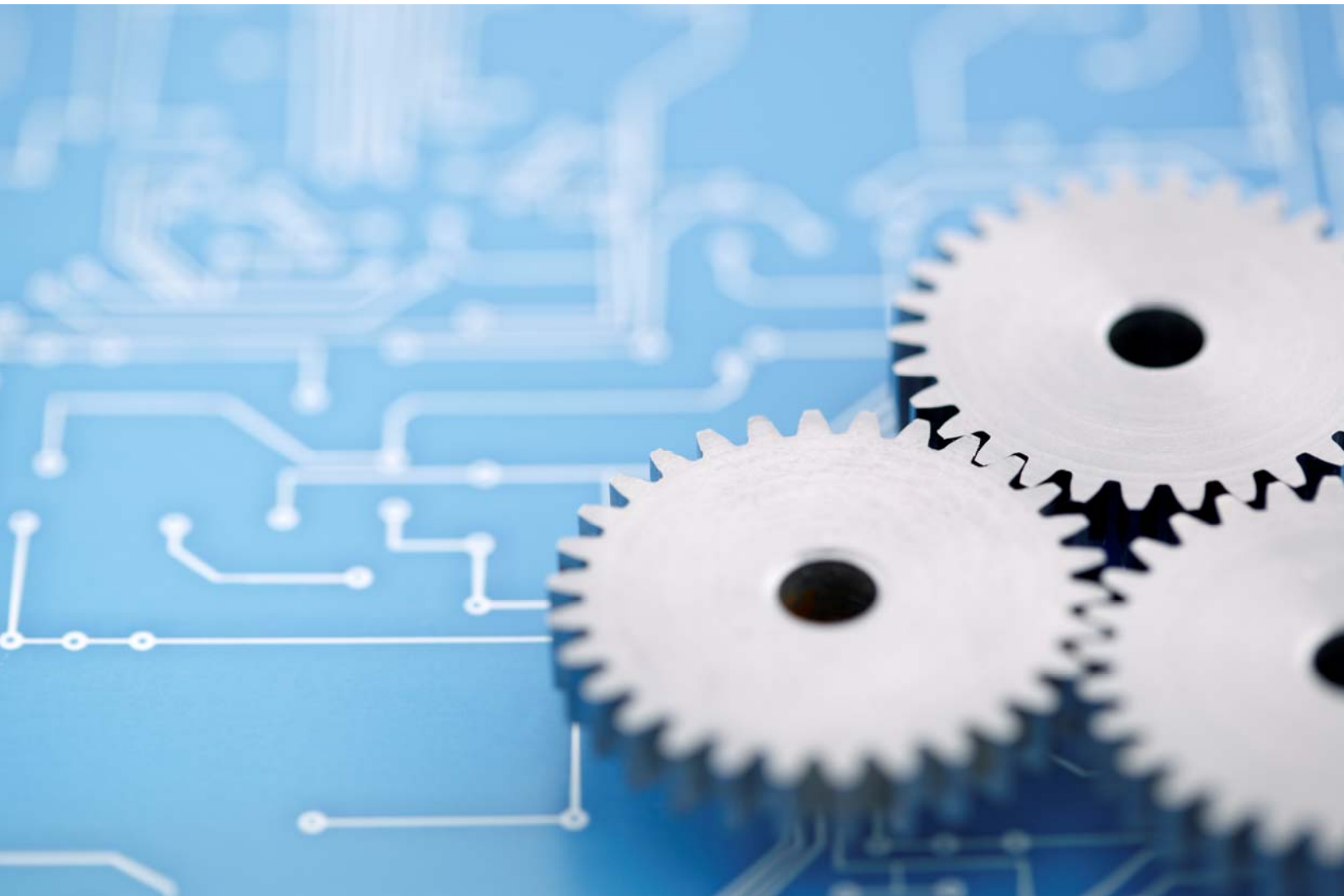




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A Guide to Low Voltage and Machinery Directive Compliance Requirements



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Introduction

Manufacturers that intend to sell their products in European Union markets must comply with the Low Voltage Directive (LVD) 2006/95/EC, which seeks to ensure that electrical equipment within certain voltage limits both provides a high level of protection for European citizens and enjoys a single market in the EU.

The Machinery Directive (MD) was established to permit the free movement of machinery within the EU market. Manufacturers of equipment that fall under the scope of the directive, such as grinding machines, lathe machines and packaging machines, must issue a Declaration of Conformity (DoC) in order to sell their products in the EU.

This white paper gives you a thorough understanding of the key elements of the Low Voltage Directive and the Machinery Directive. The Directives are legal documents (laws) issued on the authority of the Council of the EU and adopted by all member countries. They create a uniform level of requirements and regulations for all EEA members (Harmonisation of legal requirements in the member states). The Directives facilitate the free movement of goods within EU. There are many directives like ATEX, RTTE, PED, PPE, GAD, LVD, and MD.

This focus of this white paper is on:

- Low Voltage Directive (LVD) 2006/95/EC
- Machinery Directive 2006/42/EC

Electrical Safety - Low Voltage Directive

The Low Voltage Directive (LVD) 2006/95/EC seeks to ensure that electrical equipment within certain voltage limits both provides a high level of protection for European citizens and enjoys a Single Market in the European Union.

The Directive covers electrical equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current. It should be noted that these voltage ratings refer to the voltage of the electrical input or output, not to voltages that may appear inside the equipment. The LVD consists of sixteen articles and Five Annexes

The LVD is one of the oldest Single Market Directives and, although it was written before the introduction of the "New" or "Global" Approaches to such legislation. However, in broad terms, it does characterize both by providing a conformity assessment procedure to be applied to equipment before being placed on the

Market and Essential Requirements (ERs), which such equipment must meet either directly or by means of, harmonized standards.

For electrical equipment within its scope, the Directive provides the Requirements with respect to health and safety covering all risks, thus ensuring that electrical equipment is safe in its intended use.

The manufacturer is responsible for performing the conformity assessment, meaning no third-party intervention is required. So-called “notified bodies,” however, may provide reports in response to a challenge by a national authority regarding the conformity of the equipment.

The principal elements of the safety objectives referred to in paragraph 1 are listed in Annex I.

Guidelines on the application of LVD 2006/95/EC

What are the conformity assessment procedures to be applied under LVD 2006/95/EC?

Article 8 and Annex IV of the directive describe the procedure by which the manufacturer or its authorized representative established in the EC ensures and declares conformity of the electrical equipment with the provisions of the directive. This procedure includes three main elements.

1. **CE marking.** Before it is placed on the market, the electrical equipment must have the CE marking affixed. Only the manufacturer or their authorized representatives established in the EC are authorized to affix the CE marking.
2. **Technical documentation.** Before a product is placed on the market, the manufacturer compiles the technical documentation, which makes it possible to assess whether the electrical equipment complies with the requirements of the directive.
3. **Declaration of conformity (DoC).** The manufacturer or its authorized representative established in the EC are also required, and are the only ones authorized, to issue in writing a DoC (see below) before placing the product on the market.



For cases in which no standards within the meaning of the directive have been applied, the manufacturer must provide within the technical documentation a description of the solutions adopted to satisfy the safety requirements of the directive.

In case of challenge by the authorities in charge of market surveillance, a report in the sense of Article 8.2 is considered an element of proof. In the event that conformity is challenged, Article 8.2 allows manufacturers to submit a report issued by a notified body as evidence that the electrical equipment complies with the safety objectives (Article 2 and Annex I).

In certain cases, the manufacturer or its authorized representative established within the EC may ask in advance for a report to be issued by a notified body in accordance with the procedure provided for in Article 11, and to keep it together with the technical documentation. The availability of such a report would make matters easier and speedier in the event of a challenge by the authorities.

The main function of Article 8.2 is to provide the conditions most favourable to progress and dynamism in the electrotechnical industry. It facilitates the marketing of high-tech electrical equipment, which cannot benefit from the support of any technical standards because such standards are often created after the development of a technical innovation.

What is the purpose of CE marking?

- CE marking declares conformity of electrical equipment with the essential requirements and conformity assessment procedures established under the LVD and all other directives applicable to it.
- CE marking provides an understanding that safety of individuals and protection of environment have been considered in the design of equipment. It is not a mark of quality, nor is it a type mark.
- CE marking is the basic mandatory requirement to enter the EU. It is a form of legal security in the court of law, which means if there is an accident due to the misuse of the product, then your technical construction file (TCF) and DoC will shield you from legal process.
- When product is marked with CE, it is understood that it complies with all applicable directives.
- CE helps the manufacturer to freely move the product into the entire EU market, which is twice as large as the North American market.

Where should the CE marking be affixed?

The manufacturer or its authorized representative established in the EC must place the CE marking on the electrical equipment. If it is not possible to place the mark on the product, then it must be placed on the packaging, on the instructions for use or on the guarantee certificate. The CE conformity marking must be affixed visibly, legibly and indelibly.

What constitutes CE non-compliances?

- Failure to satisfy the essential requirements
- Incorrect application of the harmonized standards
- Failure to produce a TCF
- Failure to provide a DoC
- Incorrect application of CE mark
- No application of CE mark
- Missing or incomplete instructions (including the necessary translation)

What must be included in the technical documentation?

The technical documentation must include details of the design, manufacture and operation of the electrical equipment, to the extent that these details are necessary to assess the conformity of the electrical equipment with the requirements of the directive. The documentation must contain:

- A general description of the electrical equipment, design and manufacture drawings, as well as diagrams of components, subassemblies, circuits, etc.
- Descriptions and explanations that are necessary to understand the aforementioned drawings and diagrams, as well as the operation of the electrical equipment
- A list of the standards used, in full or in part, and a description of the solutions employed to meet the safety aspects of this directive when standards have not been applied
- The results of design calculations and of checks performed
- Test reports established either by the manufacturer or a third party

Who must keep the technical documentation and where?

The manufacturer or its authorized representative established in the EC must keep this documentation at the disposal of the national authorities for inspection purposes for at least 10 years from the last date of product's manufacture. The technical documentation may be kept on electronic support, provided that it is easily accessible for inspection. If the manufacturer is not established in the EC and he has no authorized representative in the EC, it is the importer's responsibility for placing the product on the EC market.

Who must keep the declaration of conformity and where?

The manufacturer or its authorized representative established in the EC. If the manufacturer is not established in the EC and has no authorized representative in the EC, then the importer or entity responsible for placing the product on the market must keep a copy of the DoC at the disposal of the national authorities for inspection purposes. The national market surveillance authorities may, when appropriate, require a copy of the DoC.

What must be included in the declaration of conformity?

Annex III.B of the directive describes the content of the DoC as follows:

- Name and address of the manufacturer or its authorized representative established within the EC
- A description of the electrical equipment
- Reference to the harmonized standards
- Where appropriate, reference to the specifications on which conformity is declared
- Identification of the signatory, who has been empowered to enter into commitments on behalf of the manufacturer or its authorized representative established within the EC
- The last two digits of the year in which the CE marking was affixed
- The DoC must be drawn up at least in one of the official languages of the EC

The responsibilities of the importer

Unless the importer is also the manufacturer's authorized representative, it will not, in general, have detailed knowledge of which directives have been considered by the manufacturer or which standards have been applied. As a consequence, the importer cannot:

- Affix CE marking
- Issue the DoC
- Compile the technical file

Cases in which neither the manufacturer nor its authorized representative are established within the EC, the importer is considered the entity first placing the product on the EC market, and is therefore responsible for ensuring compliance with the requirements.

Machinery Directive 2006/42/EC

The Machinery Directive (MD) was established to permit the free movement of machinery within the EU market. Manufacturers of equipment that fall under the scope of the directive, such as grinding machines, lathe machines and packaging machines, must issue a DoC in order to sell their products in the EU.

The Machinery Directive 2006/42/EC became effective on Dec. 29, 2009.

Declaration of Conformity

The manufacturer or its authorized representative established in the EC are required, and are the only ones authorized, to issue in writing a DoC before placing the machine on the market. There are two types of declaration:

- For the entire machine (DoC)
- For partially completed machinery (declaration of incorporation, or DoI)

DoC/DoI Requirements

- 1) DoC/DoI must accompany shipment
- 2) DoC/DoI must be signed by the “responsible” entity (the manufacturer or its authorized representative)
- 3) DoC/DoI must clearly identify:
 - a. All applicable directives and standards
 - b. The manufacturer’s name and address
 - c. The year of manufacture
 - d. The product identification reference to third party (if any)
 - e. The authorized representative’s details, if the manufacturer is based outside the EU
- 4) DoC/DoI must be part of a product’s technical file and manual
- 5) DoC/DoI must be kept for a period of at least 10 years from the last date of manufacture

Compliance Services

Your customers have high expectations. Domestic and international distribution channels, as well as end users, demand safety, reliability and rigorous compliance to existing and emerging standards. In this increasingly complex environment, you need a testing and certification partner who understands the challenges you face and has the resources and experience to help you reach global markets.

To help your organization comply with the Low Voltage and Machinery Directives, your certification partner should provide assistance in the following EN standards:

- **EN ISO 12100 2010:** Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)
- **EN 60204-1:2006/AC 2010:** Safety of machinery - Electrical equipment of machines - Part 1: General requirements IEC 60204-1:2005 (Modified)
- **EN ISO 13857 2008:** Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs
- **EN ISO 13850 2008:** Safety of machinery - Emergency stop - Principles for design (ISO 13850:2006)
- **EN ISO 13849-1:2008/AC 2009:** Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design
- **EN ISO 13849-2 2012:** Safety of machinery - Safety-related parts of control systems - Part 2: Validation (ISO 13849-2:2012)
- **EN 349:1993+A1 2008:** Safety of machinery - Minimum gaps to avoid crushing of parts of the human body

Additionally, manufacturers will have to take the EMC Directive into account, which means you'll need a certification partner that can conduct the proper testing to show compliance to:

- **CENELEC EN 61000-6-4 2007:** Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission standard for industrial environments
- **CENELEC EN61000-6-2 2005:** Electromagnetic compatibility (EMC) Part 6-2: Generic standards - Immunity for industrial environments (IEC 61000-6-2: 2005)

How intertek can help

Review of the technical construction file:

Your certification partner should review your documentation to ensure that it includes all the necessary information required by the applicable European New Approach Directives.

Conduct testing to applicable standards:

Your certification partner should conduct tests to the applicable standards and issue informative test reports.

Risk assessment facilitation:

One of the most important clauses of the Machinery Directive is Clause 1.1.2 of Annex I entitled Principles of Safety Integration. Essentially this clause requires manufacturers to conduct a hazard and risk assessment on all machinery and to seek ways of reducing risk. EN ISO 12100-2010 (EN14121) has been written to assist engineers when they are conducting a hazard and risk assessment on any type of machinery. EN 13849 has been written to assist design engineers when they are designing safety related parts of control systems. EN 13849 also provides guidance on risk assessment when considering the safety related parts of control systems.

Both EN ISO 12100-2010 (EN14121) and EN 13849 provide valuable guidance on what to consider when performing a hazard and risk assessment. They have been written to suit many situations; however, they cannot address every issue in depth. Despite this, it is interesting, that EN 13849 introduces a fairly simple way of conducting a risk assessment and if this approach is developed alongside the ideas contained in EN 14121, a single approach to hazard and risk assessment is possible.

Our experience says manufacturers need to arrive at a conclusion quickly because they have limited resources. They also need to arrive at a defined course of action without too many interactions. If a suitable group of people is assembled, we usually find that manufacturers know all the important issues that need to be considered, because they have the best knowledge of their own product. They can therefore adopt this approach and come up with valid conclusions.

Consistent with EN ISO 12100-2010 (EN14121) we recognize that the first step in conducting a hazard and risk assessment is to identify the real hazards on an item of machinery. Initially we are interested in identifying hazards that are inherent on a machine in normal and abnormal operation. We therefore concentrate on the hazards that exist when no measures have been taken to reduce the risk of injury. This puts the focus on important issues. To achieve this we make sure that service engineers, operators with experience of the type of machinery, design engineers and personnel with commercial interests are all present when we conduct a hazard

and risk assessment. We also make it clear that we do not want to quantify risk. This is important because our aim is to concentrate on potential hazards and avoid debate about the seriousness of each hazard.

A sufficient number of representatives from your company who are familiar with the industry, history (product development and safety), design (electrically and mechanically) and operation of these units will be present during the complete Hazard Analysis/Risk Assessment process,

We then invite this group of people to think of nothing more than the hazards that exist on their machine and to record these at random in a list. We do not refer to the list of possible hazards in Annex A of EN ISO 12100-2010 (EN14121) at this stage, because experience has shown us that this can steer the focus away from hazards that are unique to a particular machine. We refer to Annex A at the end of the exercise as a final check. In our experience, this approach has been highly effective and has on many occasions revealed hazards that have not previously been identified (Health and Safety Executive, 2013; BBC News Manchester, U.K., 2013)

Intertek will facilitate the representatives from your company in their Hazard Analysis and Risk Assessment and afterwards summarize and document your company's representatives' decision in an acceptable format.

Continued assistance after the Hazard Analysis/Risk Assessment facilitation will be provided by your company's representatives to ensure a complete compilation, review and agreement with all facts, assumptions, evaluations, assessments and conclusions, and

One sample, all relevant documentation and information for each unit will be provided and available during the Hazard Analysis/Risk Assessment process.

Comprehensive technical documentation service:

Each Machine placed on the European Market must have a relevant Technical file made available to the European Authorities such that they can therefore check that the Machine complies with CE requirements. The manufacturer shall ensure that has addressed all appropriate requirements in accordance with the applicable EU New Approach Directives. Intertek will review the technical file for the specific product, evaluated in accordance with the requirements of the applicable directives. This technical construction file is required to be considered CE compliant. Included will be a draft Declaration of Conformity (DoC).

The file does not have to be held in the EU but must be capable of 'being assembled and made available' by the person designated on the Declaration of Conformity (DoC) within 48hrs (but this depends upon Machine complexity).

This technical documentation must be kept for at least 10 years after the final production of the product, as mandated by the Low Voltage Directive & Machinery Directive.

Facilitate contact with notified bodies:

In cases where notified body involvement is desired or required.

Perform a quality system audit:

In cases where it is required by the directive or desired by the manufacturer.

Conclusion

By working with a compliance testing organization that has a thorough understanding of EU directives for electrical equipment and machinery, you can be confident that you're partnering with a lab that can help you throughout the compliance process - from conducting a risk assessment to preparing technical documentation.

Timely compliance with EU directives is important to your company, your stakeholders and your customers. Working with a compliance testing organization that understands your needs can help expedite the process and avoid costly delays to market.

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For more information on specific testing and certification information, please contact Intertek at 1-800-WORLTLAB, email icenter@intertek.com, or visit our website at www.intertek.com.

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