



Examples of the acceptance of self-declaration of conformity in the European Union in the fields of machinery, electrical and radio equipment

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EU Legislation on machinery, electrical equipment and radio equipment

LVD: Low Voltage Directive 2014/35/EU

EMCD: Electromagnetic Compatibility Directive

RED: Radio Equipment Directive 2014/53/EU

MD: Machinery Directive 2006/42/EC

INDICATIVE EXAMPLES OF PRODUCTS

- ✓ Household appliances;
 - ✓ Luminaires;
 - ✓ Electric motors;
 - ✓ Sound and TV broadcast receivers;
 - ✓ Office or telecom equipment such as laptops, mobile phones; GPS;
 - ✓ Equipment operating below 9 KHz, such as robotic lawnmowers, metal detectors;
 - ✓ Robots.
- * Not concerned with specialised equipment which is not considered 'low risk' and so is subject to specific EU legislation (aviation, maritime, toys, medical, etc.)

ESSENTIAL REQUIREMENTS RELEVANT TO THE EXAMPLES

- LVD
 - Health and safety.
- EMCD
 - Electromagnetic compatibility (disturbance and immunity).
- RED
 - Health and safety;
 - Disturbance and immunity (Electromagnetic Compatibility);
 - Efficient use of radio spectrum;
 - Additional public policy requirements (if delegated acts are adopted e.g. access to emergency services).
- MD
 - Health and safety.



GENERAL PRINCIPLES (1)

- **LVD/EMCD/RED/MD** are total harmonisation Directives;
- Manufacturers shall ensure that products are totally compliant with the applicable requirements and shall:
 - **Establish the Technical Documentation;**
 - **Establish and sign the Declaration of Conformity;**
 - **Affix the CE Marking:**
 - * **only in one situation (partly completed machinery) the MD includes specificities, for example does not require CE Marking;**
- Involvement of notified bodies is required only in exceptional cases under the RED and MD (see hereafter). **Hence, for the vast majority of these products, there is no third-party approval/certification.**



GENERAL PRINCIPLES (2)

- European harmonised standards prepared under Commission mandate(s) mostly follow international standards (ISO/IEC) and:
 - are voluntary;
 - their references are published in the Official Journal of the EU;
 - if they are applied, they provide a presumption of conformity with the corresponding requirements.
- Manufacturers can always be in a third state:
 - For MD: they are obliged to have a contact person in the EU for the technical file;
 - For LVD/EMCD/RED: an economic operator shall be established in the EU [when new Regulation (EU) 2019/1020 on market surveillance and compliance of products becomes applicable, i.e. as of July 16, 2021].
- Public authorities monitor compliance (post market).

CONFORMITY ASSESSMENT PROCEDURES (LVD/EMCD/RED)

- LVD:
 - No involvement of notified body.
- EMCD:
 - Discretionary to involve a notified body.
- RED:
 - For safety and electromagnetic compatibility aspects, discretionary to involve a notified body;
 - For other aspects, it is required to involve a notified body, only if harmonised standards have not been applied or do not exist.



CONFORMITY ASSESSMENT PROCEDURES (MD)

- In general and for the vast majority of products (machinery) no involvement of notified body, except for in specific circumstances.
- For high risk products (they are listed in the Directive), notified body must be involved if harmonised standards covering all essential requirements have not been applied or do not exist:
 - **Examples:** sawing machinery, machinery for woodworking, machinery for underground working, guards for removable mechanical transmission devices, vehicle servicing lifts, logic units to ensure safety functions, etc.

Procedure not involving a notified body (main elements)

- The manufacturer ensures and declares on his/her sole responsibility that the equipment concerned satisfies the requirements of the Directive that applies to it.
- The manufacturer shall establish the technical documentation which shall at least include:
 - **Description of the product;**
 - **List of harmonised standards or other specifications applied;**
 - **Results of risk assessment showing that the product is compliant (e.g. test report).**

=CE marking and EU declaration of conformity



GEOGRAPHICAL APPLICATION

- LVD/EMCD/RED are applicable to products placed on the EU market.
- MD applies to machinery placed on the EU market or put into service.
- Based on International Agreements, LVD, EMCD, RED, MD apply in:
 - **European Economic Area (EEA); and**
 - **Turkey.**

Final Considerations - Conclusions

The SDoC (Supplier's Declaration of Conformity) applied in the EU for more than 35 years has proven the following advantages:

- **health and safety of consumers can be adequately protected** by a SDoC procedure when applied in conjunction with a system of market surveillance;
- **relevant risks are quite extensively addressed by a set of voluntary European standards** (normally compatible with the international standards), facilitating at the same time innovation;
- **reduces costs** for manufacturers and time required otherwise to place products on the market;
- **facilitates trade and the free circulation** of these products on a globalised market.



Thank you for your attention

Information on the Directives and Sectoral Guidance:

http://ec.europa.eu/growth/sectors/electrical-engineering_en

https://ec.europa.eu/growth/sectors/mechanical-engineering/machinery_en

Blue Guide (Horizontal Guide):

<http://ec.europa.eu/DocsRoom/documents/18027/>