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


**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
• 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/