

# *ProductSafe*

## **Safety Guidelines and Procedures for Entrepreneurs Radio Equipment and Telecommunications Terminal Equipment (R&TTE)**

### **APPLICATION**

The **R&TTE Directive 1999/5 EC** covers some of the most technically complicated products which allow wireless transmission. They also cover Telecommunications Terminal Equipment, that is equipment that is connected to the outside of the telephone network e.g. modems and telephones.

The directive adopts two other directives, the **Low Voltage Directive** and the **Electromagnetic Compatibility Directive**. For the purposes of R&TTE there is no voltage limit for the LVD. All these directives are known also as 100A directives within the EU. With all the complications of wireless it is easy to forget the electrical safety aspects of R&TTE. The Licencing of the radio spectrum remains a national matter.



**Mobile phones, wireless network devices, some computer key boards and mice, radio control models, remote controls and many other technical devices.**

## OVERVIEW OF THE SAFETY REQUIREMENTS

The purpose of the Latvian and European law is to ensure that products placed on the market are **safe**.

A "**safe product**" is any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- the categories of consumers at risk when using the product, in particular children and the elderly.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk does not constitute grounds for considering a product to be "**dangerous**".

## LATVIAN LAW

The safety of RTTE is controlled in Latvia by the following legislation:

- Consumer Rights Protection Law, 1999
- Law on the Safety of Goods and Services, 2004
- New consolidated rules No. 561 of the Cabinet of the Ministers on conformity assessment, marketing and using electronic communication terminal equipment and radio equipment.

This legislation has transposed the requirements of the relevant European Directives into Latvian law. Producers, importers, distributors and suppliers must ensure that they comply fully with the provisions of their national legislation.

## EUROPEAN LAW

### Overview of the RTTE directive

- Wireless equipment supplied in the EU must meet the RTTE requirements including those for LVD and EMC.
- They must therefore bear the CE mark.
- Batch number and or serial number.
- Name of the manufacturer.
- The identification number of the notified body if one has been used.
- The alert sign (only for class 2).



### Documentation – required information

- Information about intended use.
- Countries where the equipment can be used ( Class 2 ).
- Indication of potential restrictions.
- Interfaces of the public telecom networks to which the equipment can be connected.
- Information for the user in the national language.

### Declaration of Conformity

There can be a copy with the product or a reference to where it can be found for example a web address.

### Definitions

**'Radio Equipment'** - is defined as a product, or relevant component thereof, capable of communication by means of emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space communication.

**'Telecommunications Equipment'** - is defined as a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks

**'Manufacturer'** – is described as the legal entity (often described as the “person” in legislation) responsible for the design and construction of the apparatus with a view to placing it on the market on his own behalf. The manufacturer may subcontract some of these functions without losing his status as the manufacturer. For example, he can use ready-made sub-assemblies or components, or may sub-contract the assembly work. Anyone altering apparatus significantly, and placing it on the market, is also deemed to be a manufacturer for the purpose of the directive.

**'Authorised Representative'** - (as in the R&TTE Directive) may be appointed expressly by a manufacturer to act on behalf of the manufacturer in certain circumstances. If an authorised representative is appointed, he must be based in the EEA. If so appointed, the authorised representative may, at the request of the manufacturer, sign the declaration of conformity and affix the CE mark. If the manufacturer is based outside the EEA, the authorised representative may hold documentation and evidence of conformity in the EEA. If he takes on these responsibilities, he may be subject to enforcement action in a case where apparatus is non-compliant.

**'Importer'** – is the person who places apparatus (from a manufacturer based outside the EEA) onto the EEA market. The importer should keep the declaration of conformity and supporting evidence, and if he does not, must be able to obtain it from the manufacturer promptly in the case of a request by the enforcement authorities. An importer cannot sign a declaration of conformity, nor affix the CE mark.

**'Telecommunications terminal equipment'** – is a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks. Public networks are those used wholly or partly for the provision of publicly available telecommunications services.

**'Radio equipment'** – any product, or relevant component of a product, capable of communication by means of emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radio communication.

**'Radio waves'** – are electromagnetic waves of frequencies from 9 kHz to 3000 GHz which propagate in space without artificial guide, such as a waveguide.

## Exclusions

The directive does not apply to:

- amateur radio kits,
- cable and wiring,
- civil aviation equipment.
- certain marine equipment,
- broadcast receivers and

## Classes of Equipment

- **Class 1** - Equipment operating on harmonised frequencies.
- **Class 2** - Equipment **not** operating on harmonised frequencies.

The Commission has published a list of subclasses on its website at [www.europa.eu.int/comm/enterprise/rtte](http://www.europa.eu.int/comm/enterprise/rtte)

## Notifications

- Equipment not operating on harmonised frequencies must be notified to the national authority.

## National Radio Interface Requirements

- There will be national interface requirements for different types of devices for example short range devices such as movement alert detectors.
- These are detailed and are an important consideration when checking frequencies are in band.

## Checks for entrepreneurs to carry out

- Entrepreneurs should check for the CE mark, the alert symbol and other labelling as previously described. It is good practice to look out for suspicious product e.g. those without a brand name or a bar code or other unusual signs.
- Because it is not possible to tell visually whether there is a problem with equipment, entrepreneurs should always ensure that the documentation is complete and appropriate. Those entrepreneurs placing the goods on the market are obligated to cooperate with market surveillance authorities.
- If the paperwork is not satisfactory or if it is not available, the product must not be supplied. If a test shows that equipment is operating out of band, you should not supply the product and notify the CRPC.
- If the product is considered dangerous it is likely to be banned and information passed to the other market surveillance authorities.
- In addition the **RAPEX** procedure of the General Product Safety Directive should be used if there is a serious risk for consumers.
- All electrical products supplied with the equipment can also be examined for compliance.

The vast majority of equipment available does not present a problem and many low power devices do not present a danger. Experience has shown that it is electrical safety in the low priced end of the market for these goods that is the main problem e.g. cheap radio controlled models.

**Note:-**Apparatus which has still to be made to comply with the directive may be displayed at trade fairs, exhibitions and demonstrations, etc. provided that a **visible sign** clearly indicates that such apparatus may not be marketed or put into service until it has been made to comply.

## Interactions with other Directives

- **Medical Devices and Active Implantable Medical Devices**

Apparatus that incorporates, either as an integral part or an accessory, a medical device within the scope of Directive 93/42/EEC or an active implantable medical device within the scope of Directive 90/385/EEC, is governed by the provisions of the R&TTE Directive but without prejudice to the requirements of those directives. The directives therefore apply in a complementary way and the requirements and procedures of each applicable directive must be met.

- **Motor Vehicles**

Apparatus that is also a component or separate technical unit of a vehicle or a two- or three-wheeled motor vehicle is also governed by the provisions of the R&TTE Directive, similarly without prejudice to the provisions of the other directives.

## Placing on the market

The definition of placing on the market is an important one, as this is the point that the directive starts to apply. In some national legislation, the term "supply" is used to describe this point but the terms may be considered to be equivalent. This is the point at which the apparatus passed from the manufacturing stage to the market. It may be represented by a physical handover, or as a change of ownership. The latter is particularly relevant in the case of large systems and installations which may take some time to build and install. As explained above, apparatus is not placed on the market by being displayed in catalogues, or at trade fairs or exhibitions. However, a notice should be provided to indicate that it is not yet compliant with the directive.

**Note:-** Apparatus is not considered to be placed on the market if it is intended to be exported (or re-exported) to a country outside the Community. This exclusion is valid only if the CE mark has not been applied at that stage.

## Conformity assessment

Apparatus meeting the requirements of the relevant harmonised standards whose references have been published in the Official Journal are presumed to be in compliance with the essential requirements. For many products, more than one standard will be required. For example, a piece of radio equipment may have a standard for EMC, one for safety compliance, one for compliance with the requirement for effective use of the radio spectrum, and finally a standard covering some additional essential requirements.

The directive describes four procedures for conformity assessment, one of which must be used to demonstrate compliance with all the relevant essential requirements, subject to an alternative for the EMC and LVD essential requirements. These are described in Annexes II, III, IV and V of the directive.

As an alternative for compliance with the essential requirements in respect of Article 3(1)(a) Safety and 3(1)(b) EMC, the procedures in 73/23/EEC and 89/336/EEC may be used respectively for those aspects, for apparatus within the scope of those directives. The alternative means of demonstrating compliance are contained within those directives.

### **Selection of routes to compliance**

There are several possibilities for demonstrating compliance and these are set out in the Annexes to the Directive as follows:

- **Annex II Internal Production Control**
  - **Annex II Internal Production Control Plus Specific Apparatus Tests**
  - **Annex IV Technical Construction File**
  - **Annex V Full Quality Assurance**
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- For **telecommunications terminal equipment** that does not make use of the spectrum allocated to terrestrial/space radio communications, and for the receiving parts of radio equipment, the manufacturer may use the procedures of Annexes II, IV or V of the Directive.
  - For **radio equipment** not within the scope of the above paragraph, the manufacturer may choose from Annexes III, IV or V where relevant harmonised standards have been applied in full, or Annexes IV or V where harmonised standards have not been applied, or have been applied only in part.

### **Application of Harmonised Standards**

A standard is described as '**harmonised**' if it has been produced by one of the European standards bodies and accepted as a relevant standard under one or more directives by the European Commission. The standards bodies are:

- CEN The European Committee for Standardisation
- CENELEC The European Committee for Electrotechnical Standardisation
- ETSI European Telecommunications Standards Institute

These organisations produce standards with a number which is prefixed by "**EN**" (European Norm).

The Commission publishes lists of standards that are harmonised under each directive from time to time in its Official Journal of the European Union (commonly referred to as the "**Official Journal**").

## Electro-magnetic compatibility (EMC) standards

There are three types of EMC standard: product family, generic, and basic.

- **Product family** standards describe limits, and sometimes test methods for the demonstration of conformity. Other product family standards refer to basic standards for the test methods.
- **Generic** standards apply in cases where a product family standard is not applicable, and contain limits with references to basic standards for the test methods.
- **Basic** standards describe test methods but do not contain specific requirements or limits.

The list in the Official Journal contains product family and generic standards only. This is because basic standards cannot themselves provide a presumption of conformity because they do not contain specific requirements.

These standards have a hierarchy of application. Product standards take precedence over generic standards. The latter are only employed if a more specific standard does not exist for the product concerned.

Product standards themselves have a hierarchy in that some are more specific than others. In selecting product standards, therefore, the manufacturer should choose a product-specific standard over a product family standard if the former covers the apparatus concerned.

In selecting the appropriate standards, care should be taken to check the scopes of the standards concerned. The scope is often wider than the title of the standard would suggest.

If generic standards apply, they should be chosen based on the intended environment for the apparatus.

There are two possible environments:

- residential, commercial and light industrial
- industrial

The residential, commercial and light industrial emission standard has more restrictive emission limits than the industrial emission standard because of the greater chance of radio receivers in proximity. The industrial generic has higher immunity requirements (greater levels of disturbances that the apparatus must withstand) when compared with the residential, commercial and light industrial immunity standard.

## Declaration of Conformity

Whichever route to compliance is chosen, when the manufacturer is satisfied that the apparatus meets the requirements of the directive, he draws up a declaration of conformity. The directive requires that the manufacturer holds this declaration "at the disposal of the competent authority for **ten years** following the placing of the apparatus on the market".

"**Competent authorities**" - are the regulatory bodies in each Member State.

"**At the disposal of**" - means that the declaration has to be retained for possible inspection by those responsible for enforcement of the directive. The directive and the declaration of conformity apply to each individual product. The ten-year requirement to retain the declaration of conformity therefore begins when the last product has been placed on the market. The declaration of conformity is drawn up by the manufacturer, or if he so chooses, his authorised representative. The manufacturer does not have to be based in the EEA, and the declaration is valid wherever it is drawn up.

## CE Marking

All apparatus covered by the directive must bear the **CE mark**. This mark indicates that the apparatus meets the requirements of all applicable directives, and has the form shown in the diagrams below:



The grid in the diagram on the right is to show the relative dimensions and is not part of the marking. The "**CE**" may be any size providing the proportions are maintained but must not be shorter than **5 mm** in height. The CE mark must be applied to the apparatus, or if that is not possible, in descending order of priority to the packaging, instructions for use, or guarantee certificate. It is appropriate, but not mandatory, to apply the CE mark to the packaging as well as the apparatus. This allows the mark to be seen without opening the packaging, and will facilitate the free movement of goods. The mark must be affixed visibly, legibly and indelibly.

### **Additional marking**

In addition to the CE mark, the apparatus must carry the following information, prominently displayed:

- for telecommunications terminal equipment, identification of the interfaces of public telecommunications networks to which it is intended to be connected.
- for radio equipment, the equipment class identifier must be included where an identifier has been assigned. The user is also required to be alerted to potential restrictions on use or requirements for authorisation of use in certain member states.



**Class 2** products must be identified by the so-called “**alert**” symbol, as shown.

The symbol consists of an exclamation mark inside a circle, and signifies that the frequency band that the apparatus employs is not harmonised throughout the Community and/or that potential restrictions on the use of the apparatus exist in one or more member states. It is placed on the product in addition to the CE marking. If the alert symbol is required, it must have the same height as the initials “CE”.

### **Information requirements**

The manufacturer, or the person responsible for placing the apparatus on the market, must provide information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements.

For radio equipment, this information must also include geographical restrictions on use (by country or area) which must be identified on the packaging and in the instructions for use, and the equipment class identifier, and where appropriate that the apparatus uses frequency bands which are not harmonised throughout the Community, and therefore that authorisation for use in certain member states may be required.

For telecommunications terminal equipment, there must be sufficient information to identify the interfaces of public networks to which it is intended to be connected.

### **Co-ordination across Europe**

Member State administrations meet at so-called administrative cooperation meetings where senior level regulators and enforcement bodies discuss matters of policy. Co-operation at the working level is by informal communications and via a body called PROSAFE. This is an organisation set up by European enforcement officers, and stands for Product Safety Enforcement Forum of Europe. This organisation provides a means of communication to raise awareness of activities in each Member State, and coordination of enforcement activity. Sometimes, joint enforcement projects are undertaken.

## SOURCES OF FURTHER INFORMATION

The text of the R&TTE Directive:

<http://europa.eu.int/comm/enterprise/rtte/dir99-5.htm>

List of harmonised standards applicable under the R&TTE Directive:

<http://europa.eu.int/comm/enterprise/rtte/harstand.htm>

Decisions of the European Commission in respect of the R&TTE Directive:

<http://europa.eu.int/comm/enterprise/rtte/decision/present.htm>

List of Notified Bodies under the R&TTE Directive:

<http://europa.eu.int/comm/enterprise/rtte/nb.htm>

The text of the Low Voltage Directive, as amended:

[http://europa.eu.int/comm/enterprise/electr\\_equipment/lv/direct/text.htm](http://europa.eu.int/comm/enterprise/electr_equipment/lv/direct/text.htm)

Commission Guidelines on the implementation of the Low Voltage Directive:

[http://europa.eu.int/comm/enterprise/electr\\_equipment/lv/guides/index.htm](http://europa.eu.int/comm/enterprise/electr_equipment/lv/guides/index.htm)

List of harmonised standards applicable under the Low Voltage Directive:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/lvd.html>

List of Notified Bodies under the Low Voltage Directive:

[http://europa.eu.int/comm/enterprise/electr\\_equipment/lv/nblast.htm](http://europa.eu.int/comm/enterprise/electr_equipment/lv/nblast.htm)

The text of the EMC Directive, as amended:

[http://europa.eu.int/comm/enterprise/electr\\_equipment/emc/directiv/text.htm](http://europa.eu.int/comm/enterprise/electr_equipment/emc/directiv/text.htm)

List of harmonised standards applicable under the standards route for demonstration of conformity with the EMC Directive:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/emc.html>

Commission Guidelines to the implementation of the EMC Directive:

[http://europa.eu.int/comm/enterprise/electr\\_equipment/emc/guides/index.htm](http://europa.eu.int/comm/enterprise/electr_equipment/emc/guides/index.htm)

List of Competent Bodies under the EMC Directive:

[http://europa.eu.int/comm/enterprise/electr\\_equipment/emc/cblast.htm](http://europa.eu.int/comm/enterprise/electr_equipment/emc/cblast.htm)

List of Notified Bodies under the EMC Directive:

<http://europa.eu.int/comm/enterprise/newapproach/legislation/nb/en89-336-eec.pdf>