

The new R&TTE Directive 1999/5/EC

Detailed Guidance for

**Manufacturers, Representatives and Persons
responsible for placing on the market
about:**

Responsibilities

Declaration of Conformity (DoC)

Product Marking

User Information

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This Paper shall give

advice to

- **manufacturers** and their **authorised representatives**,
- **importers**,
- **distributors** and
- **persons** responsible for **placing R&TTE** apparatus on the **EEA-market**

shall determine their responsibilities,

and how to

- fulfil the requirement of the **R&TTE- Directive**
- draw up the written **declaration of conformity (DoC)** and
- affix the correct **markings** on
 - the product or its data plate
 - the packaging and
 - the accompanying documents
- supply **information** to the **user**

2. Responsibilities

The responsibilities are also stated in the **chapter 3 of the “blue guide”**.
Some of the statements are given below:

2.1 The manufacturer

- A **manufacturer** is the person who is responsible for **designing and manufacturing a product** with a view of **placing it** on the **Community market** on **his own behalf**.
- The **manufacturer** has the **obligation to ensure** that a product intended to be **placed** on the **Community market** is **designed and manufactured**, and its **conformity assessed to the essential requirements** in accordance with the provisions of the applicable New Approach directives.
- The **manufacturer** must always **retain the overall control** and have the necessary competence to take the **responsibility** for the product.

2.2 The authorised representative

- The **manufacturer** may **appoint** any natural or legal person to act **on his behalf** as an **authorised representative**.
- The **authorised representative** must, in order to be able to act on behalf of the manufacturer, be established **inside the Community**.
- The **authorised representative** is explicitly **designated** (written mandate) by the **manufacturer**, and he **may be addressed** by the **authorities** of the Member States **instead of the manufacturer** with regard to the **latter's obligations** under the directive in question.
- The **manufacturer remains** generally **responsible** for actions carried out by an authorised representative on his behalf.
- Commercial representatives of the manufacturer, whether or not established inside the Community, are not to be confused with the authorised representative according to the directives.
- An **authorised representative cannot modify** the product on **his own initiative** in order to bring it into line with the applicable directives.

2.3 The Importer / Person responsible for placing on the market

- An **importer** (the person responsible for placing on the market) – in the meaning of New Approach directives – is any natural or legal person **established in the Community** who **places** a product from a **third country** on the **Community market**.
- The natural or legal person, who **imports** a product into the **Community** may, in some situations, be considered as the person who must assume the **responsibilities** placed on the **manufacturer** according to the applicable New Approach directives.
- The **importer** must ensure that he is able to provide the market surveillance authority with the **necessary information** regarding the product, where the **manufacturer is not established in the Community**, and he has **no authorised representative in the Community**.
- The **importer** must ensure, in order to fulfil his responsibilities, that a **contact with the manufacturer** can be established.
- Where an **importer** takes the initiative to **affix the CE** mark or **where he declares** that a product **can be used** in other Member States as those identified by the manufacturer, he becomes **responsible** for the product and **declares himself** as the **legal entity**, on which the **tasks** of the manufacturer **fall**.

2.4 The Distributor

- A **distributor** is to be considered as any natural or legal person in the supply chain who takes subsequent **commercial actions after** the product **has been placed on** the Community market.
- The **distributor** should **know**, for instance, **which products** must **bear** the **CE** marking, **what information** (e.g. the **DoC**) has to **accompany the product**, what are the **language requirements** for users instructions or other accompanying documents, and **what is** a clear **indication** of the product being **non-compliant**.
- The **distributor** may **not supply** products that he knows or should have presumed, on the basis of information in his possession and as a professional, **not to be in compliance with the legislation**.
- The **distributor** should inform the **national surveillance authority on non-compliant products** and product risks, and co-operate in actions taken to avoid or minimise these risks.
- The **distributor** must also **be able to identify the manufacturer**, his **authorised representative** in the Community, the **importer** or the person who has provided him with the product in order to **assist the surveillance authority** in its efforts to **receive the declaration of conformity** and the necessary parts of the **technical documentation**

2.5 The Assembler, installer and user

- Where an **assembly**, an **installation** or other **manipulations** may have an impact on maintaining the **compliance** of the product, the **person responsible** for such **manipulations** must **ensure** that they **do not cause a non-compliance** with the **essential requirements**.

3. Declaration of Conformity (DoC)

3.1 Content of the “Declaration of Conformity”

Concerning the **layout** (format) it is recommended to **apply** Annex A of **EN45014** "General criteria for supplier's **declaration of conformity**" (see also ISO/IEC Guide 22:1996) together with the elements mentioned in chapter 5.4 of the “blue guide”.

As a minimum the following **information** must be **provided** in the **declaration**:

- the name and address of the **manufacturer** or his **authorised representative** issuing the declaration (contact information);
- the **identification of the product** (**name, type or model number**, and any relevant **supplementary information**; e.g. **lot, batch or serial number**, sources and numbers of items);
- the **referenced standards** or other **normative documents** (e.g. national technical standards and specifications) in a precise, complete and clearly defined way;
- all **supplementary information** that may be required (e.g. grade, category), if applicable;
- a **statement** that all **essential radio test suites** have been **carried out** (applicable for transmitting radio-equipment – see Annex III and IV of the R&TTE directive);
- a statement that the product is in conformity to **all applicable essential requirements of all applicable directives**;
- **the date of issue** (of this Declaration of Conformity);
- **signature** and title or an equivalent marking of an **authorised person**;
- the statement that the declaration is issued under the sole **responsibility of the manufacturer** and, if applicable, his **authorised representative**.

It is **recommended** to also include:

- a **reference** to the **conformity procedure** which has been followed;
- the **identification number** of the **notified body** when it has been **involved** in the conformity assessment procedure (see below), preferably also his **name and address**;
- the **name and address** of the **person** who **keeps** the **technical documentation** in the Community.

4. Product marking

4.1 Product identification marking

The **manufacturer** has to **identify** the apparatus. In consultation and in agreement (contract) with the **person responsible for placing the product on the market**, the person responsible for placing the apparatus on the market (reseller) can **allow the manufacturer** to put the **resellers (brand)name** on the product. The **responsibility** for the conformity of the apparatus **remains** however with the **manufacturer**. The **reseller** must **be able to give information** on the **real manufacturer**.

4.2 Product conformity marking

4.2.1 Marking on the apparatus

4.2.1.1 CE conformity marking

1. The **CE** conformity marking must consist of the initials "**CE**" in the usable known layout. If the CE marking is reduced or **enlarged**, the **proportions** must be respected.
2. The **CE** marking must have a height of at **least 5-mm** except where this is not possible on account of the nature of the apparatus.
3. The **CE** marking must be **affixed** to the **product or to its data plate**. Additionally it must be affixed to the **packaging**, if any, and to the **accompanying documents**.
4. The CE marking must be affixed **visibly, legibly and indelibly**.
5. If **one or more notified bodies** are involved during the conformity assessment procedure (Annex III, IV or V), then the identification number(s) of **the involved notified bodies must follow the initials "CE"**.
6. The **CE** marking on the product may **not be omitted** nor be moved to the packaging or accompanying documents **on purely aesthetic reasons**.
7. The requirement for **visibility** means that the **CE** marking must be **easily accessible** for **market surveillance authorities**. It must be **visible** for **distributors, users and consumers**.
8. The requirement for **indelibility** means that the **CE** marking must **not be removed** from the product without **leaving noticeable traces** under normal circumstances. However, **this does not mean** that the **CE** marking **must form an integral part of the product**.

4.2.1.2 Equipment Class Identifier for Radio Equipment

There are two main categories of radio equipment.

- **all radio equipment** that can be **used without any restriction** in the whole Community. **No sign** is attributed to this category for the identification of the equipment category (i.e. no supplementary marking).
- **any other radio equipment**, i.e. **radio equipment** for which there is some sort of **restriction in the use**. The **packaging and the users manual** must contain more **information** about this.
If the apparatus **makes use** of **radio frequency** bands where their use **is not harmonised**, the **equipment class identifier** must attract the **users attention** to this fact.

This identifier can **only** be **applied** if the **equipment class has been assigned**.

The following **graphic symbol** was adopted as the **alert- sign** for indicating the **category** :

(!) It must have the **same height** as the initials "CE".

4.2.2 Marking on the packaging and in the “instructions for use”

The **CE-sign** and the **alert-sign** (equipment class identifier) have to be also on the packaging and the instructions for use.

The following items should be considered for **all radio equipment**:

- The information on the **intended use** shall be on the **packaging and** in the “**instructions for use**” of the apparatus.
- The “**instructions for use**” should include a **table** or **other statement** indicating **where** (country, countries or regions) the radio-equipment is **intended to be used** and **if** an **authorisation** (e.g. individual or general licence) is **needed** to **legally use** the radio equipment.

If it is **clearly indicated** on the **packaging**, these **restrictions** are **allowed to be on the accompanying documents**.

It is necessary that possible restrictions be stated **in the language of the region** where the **restriction applies** and in the **language of the region** where the product is sold.

Manufacturers should **indicate**, even for **receiving equipment**, **where it is intended to be used**. For **receiving equipment**, which is **not allowed to be used** for other reasons than those covered by the Directive (e.g. radar-warning apparatus), they should in general terms **indicate**, that **usage may be constrained**.

4.3 Overview of the product conformity marking

Radio Equipment		
Conformity Assessment Procedure according to	frequency band is harmonised	frequency band is not harmonised
Annex II (internal production control) (receive only radio equipment)	CE	CE
Annex III (Annex II + specific product tests) (use of harmonised standards)		
Radio tests in Harmonised Standard	CE	CE ⚠
Radio tests <u>not all</u> in Harmonised Standard	CE 0678	CE 0678 ⚠
Annex IV (technical construction file) or Annex V (Full Quality assurance)	CE 0678	CE 0678 ⚠

