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Radio Equipment Directive (RED) 2014/53/EU

Contents

CE marking

CE marking has existed in its present form since 1993. CE stands for “Conformité Européenne”, which in practice means that it “conforms to European directives”.

CE marking of a product means that it complies with the legal requirements placed on the product within the EEA and, therefore can be sold there. The manufacturer or their authorised representative gives the product its CE marking and is liable for ensuring that the product complies with the requirements of the directives.

The primary purpose of CE marking is to facilitate free trade of goods within the EU trough harmonising laws concerning safety, health and the environment within the EU.

Directives

Directives are high-level legal acts that the various countries, in turn, make into national laws. Although there are hundreds of directives overall, there are only a few directives that are relevant for a given product. Relevant directives may cover areas such as electrical safety, energy or EMC compliance and may also cover special product categories. The latter is typically for product categories that are regarded as having high risks, such as medical equipment or machinery.

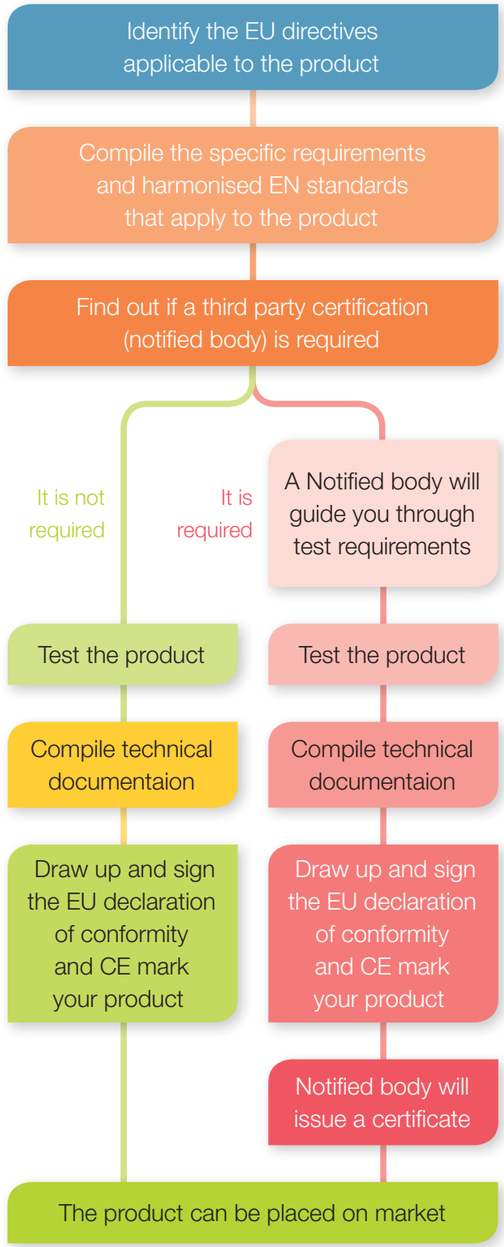
The Directives are, however, often quite short, and very general. For instance, the Low Voltage Directive states that a product is to protect the “health and safety of persons, of domestic animals and property”. This is vague and hard to demonstrate. Standards, in contrast, are specific and detailed.

Standards

As directives often are quite general when setting goals for e.g. safety, they refer to harmonised standards. These standards can either be product-specific, such as the safety standard for an electric toaster or be general, covering, for instance, protection against water. These latter standards are often called “horizontal standards” as they are valid for all product categories. The standards set very detailed technical requirements, and one standard may easily be 100+ pages. A harmonised standard requires technical competence to understand, and the tests described in a standard require a specially equipped laboratory. Some of the required equipment may be very general, such as temperature loggers, while others may be specific to only a single standard. Some equipment, for instance, for EMC and radio testing, may cost up to one million USD. The standards referred to by the different directives, often called Harmonised standards, are listed on a specific EU web page.

If you have read the step-by-step guide to CE marking, then you already know that the first step is to identify the relevant directives and standards. If you have not, we recommend starting with the step-by-step guide to get an overview of the CE marking process before you go more in-depth by learning more about the respective directives.

In this e-book, we will look more in-depth at one of the directives, the Radio equipment directive.

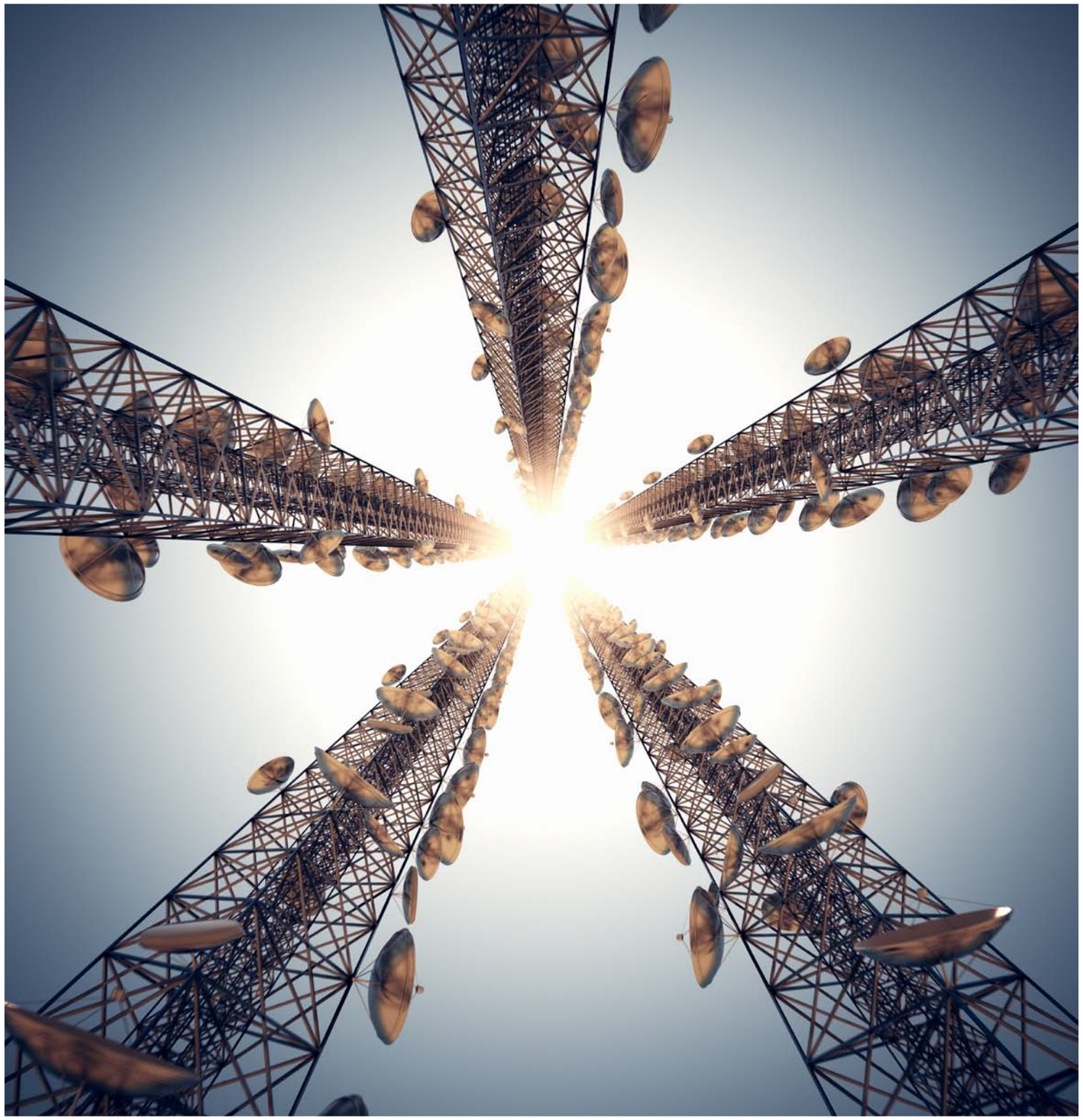


Radio Equipment Directive (RED) 2014/53/EU

The Directive establishes a regulatory framework for placing radio equipment on the market. It ensures a single market for radio equipment by setting essential requirements for safety and health, electromagnetic compatibility (EMC) and the efficient use of the radio spectrum.

It also provides the basis for further regulation governing some additional aspects. These include technical features for protecting the privacy and personal data and against fraud. Furthermore, additional aspects cover interoperability, access to emergency services and compliance regarding the combination of radio equipment and software.

The RED also covers requirements in the low-voltage directive (LVD) and the EMC directive.



Which products are covered under the RED?

Equipment that intentionally emits or receives radio waves for the purpose of radio communication or radiodetermination makes systematic use of the radio spectrum. Most wireless products, including products with WiFi, Bluetooth and similar technologies.

A few examples of devices are

- Mobile phones
- Laptops
- Radars
- Broadcasting devices
- Smartwatches
- Routers
- Babycalls
- Monitoring systems
- Medical implant

A medical device that contains wireless function is subject to both Medical Device Regulation and RED because RED does not cover the general safety and performance requirements (SPRs) of MDR.

If a device that contains a wireless card is also subject to another directive and the essential requirements of that directive are not covered already by RED, then compliance must be declared concerning both directives.

Essential requirements

The essential requirements of the Radio Equipment Directive are that radio equipment must be constructed to ensure:

Art. 3.1a. The protection of health and safety of the user and any other person
Art. 3.1b. Adequate level of Electromagnetic Compatibility (EMC)
Art. 3.2. Effective use of the radio spectrum to avoid harmful interference
Art. 3.3. Meets any Special requirements

Art. 3.1a) The protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying

Art. 3.1b) An adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU

Art. 3.2) Radio equipment shall be constructed to effectively use and support the efficient use of radio spectrum in order to avoid harmful interference

Art. 3.3) Radio equipment within certain categories or classes shall comply with the following essential requirements:

a) radio equipment interworks with accessories, in particular with common chargers
b) radio equipment interworks via networks with other radio equipment
c) radio equipment can be connected to interfaces of the appropriate type throughout the EU/EEA
d) radio equipment does not harm the network or its functioning, or misuse network resources, thereby causing an unacceptable degradation of service
e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected
f) radio equipment supports certain features ensuring protection from fraud
g) radio equipment supports certain features ensuring access to emergency services
h) radio equipment supports certain features in order to facilitate its use by users with a disability
i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated

How to show compliance

CE marking is not proof of compliance; the technical construction file behind the product is. Normally, a technical construction file should contain relevant information about the design, manufacture and use of the product. In other words, it contains everything to demonstrate that the essential requirements imposed on CE marked products have been fulfilled.

Some examples of this are:

- A general product description
- Design information (for example wiring diagrams, design drawings, mechanical drawings, parts list, manufacturing documentation, etc.)
- Descriptions and explanations necessary to understand the above-mentioned drawings
- Installation instructions and user manual/guide for the product. The installation instructions should clarify how to install and use the product. The user guide shall be written in the language of the country in which the product is to be sold.
- A list of the standards applied, either in full or in part, or own standards/methods used to demonstrate compliance with the directive
- Other data used or that may be of benefit (for example, calculations, simulations, etc.)
- Test reports
  A test report is obtained by testing the product in accordance with harmonised standards. A harmonised standard is a European standard that provides solutions for compliance with a legal provision. The testing requires a well-equipped electrical laboratory, normally with some equipment specially for the given standard. It also requires the tests to be carried out by experienced personnel

Relevant tests to show compliance

- RF Output Power
- Power Spectral Density
- Duty cycle, Tx-Sequence,Tx-gap
- Accumulated Transmit time, Frequency Occupation & Hopping Sequence
- Hopping Frequency Separation
- Medium utilisation
- Adaptivity
- Occupied Channel Bandwidth
- Transmitter unwanted emissions in the OOB domain
- Transmitter unwanted emissions in the spurious domain
- Receiver spurious emissions
- Receiver Blocking
- Geo-location capability

Important dates

June 2016	RED replaced the previous directive R&TTE 1999/5/EC.
June 2017	All radio products must comply to the RED directive.
February 2022	EU Commission decided to implement Article 3.3. d. e and f to cover cyber security in the RED.
August 2024	The cyber security requirements will become mandatory.

Cybersecurity is becoming mandatory

For all practical purposes, this means that cybersecurity becomes a mandatory requirement for CE marking just as electrical safety, EMC and radio already are.

The scope of these requirements covers most wireless products under the RED, which are connected to the internet, directly or indirectly. For products to be used by children or for childcare, the cybersecurity requirements apply even if the products are not connected to the internet.

The requirements become mandatory on 1 August 2024, which means this needs to be considered for all products intended for sales after this date. Harmonised standards are, however not expected to be published until late 2023 – at best.

There are, however, standards already published which are expected to give good coverage of the coming standards, such as ETSI EN 303 645 for consumer IoTs and IEC 62443 for industrial products.

As for other areas, RED Notified Bodies (NB) having cybersecurity in their scope can issue RED certificates also before harmonised standards are published.

Additional resources

- Bringing your radio device to the EU market in 6 simple steps
- Your complete guide to the most common terms in CE marking
- CE + CE = CE?
- It is finally decided cyber security will become required for CE marking!
- Do you know the seven tips for successful EMC testing?
- The benefits and downsides of using radio modules in North America

What can Nemko offer?

- Guidance/report to help you determine which standards apply to your product
- Workshops for you and your organisation to improve the understanding of CE marking requirements for your product
- Test plan
- Testing in accordance to the relevant standards
- Test reports
- Risk analysis
- Quality Management (ISO)
- Documentation of the manufacturing processes, e.g. factory inspection
- Certifications to show compliance
- Market access services worldwide
- Notified Body services
- Pre-compliance services
- Standard surveillance services

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