



Conformity assessment procedures for Radio Equipment Directive Scheme

RD_061, Issue 10

This guide describes the certification services of 0063 for manufacturers and importers to realise that their radio equipment can be placed on the European market.

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1 Introduction

1.1 About the unit Wireless & EMC (Kiwa)

Kiwa Nederland (unit Wireless & EMC), hereinafter to be referred to as Kiwa) is a third party test laboratory and third party certification body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited the unit wireless & EMC (legal entity of Kiwa NL B.V.) to ISO/IEC 17025 (laboratory) and NEN-EN-ISO/IEC 17065 (product certification).

More information about Kiwa Nederland (unit Wireless & EMC), is available in *RD_560*.

1.2 About this document

This document lays down the procedures for the Economic operators (manufacturers, authorized representatives, importers and distributors) who want to apply for the services of Kiwa in order to meet the requirements of the Radio Equipment (RE) Directive 2014/53/EU, when placing their products on the market of the European Union.

Described are the conformity assessment procedures that have to be followed before these products may be placed on the market and how to act when modifications to such products are made. The added value of the services of Kiwa is given. When the assistance of a Notified Body is needed a description is given of the implementation of these services by Kiwa. The Notified Body services are derived from the conformity assessment procedures as defined in the Annexes III and IV of the European RE Directive 2014/53/EU.

Furthermore this document gives information how to act when modifications to equipment are made. It also describes specific conditions, such as markings on the products, declarations to be drawn up, etc., which economic operators will have to deal with when using a conformity assessment procedure with or without the involvement of a Notified Body.

1.3 The Transition from R&TTE to RED

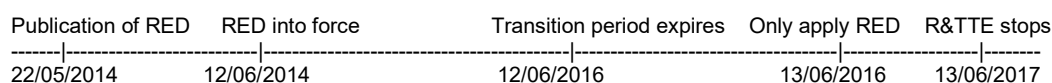
The current R&TTE Directive 1999/5/EC will be withdrawn and cancelled on June 20, 2016, and the new European Radio Equipment Directive (RED) 2014/53/EU will become mandatory on that date.

The RED has been published in the Official Journal of the European Commission on May 22, 2014. The RED has entered into force on June 12, 2014 and the transition period will expire on June 12, 2016. From June 13, 2016, all member states must apply the new Radio Equipment Directive. The repeal date for the current (old) R&TTE Directive 1999/5/EC is June 12, 2016, and products compliant to the old Directive can be placed on the market for one additional year until June 13, 2017 (After this transition period, the R&TTE Directive will no longer apply).

All equipment placed on the market after 13 June 2017, will need to meet the requirements of the RED. That means also the old equipment which was based on R&TTE.

Under the new RED, Notified Bodies (NBs) will issue only a NB EU-type examination Certificate after June 2016, not a NB Opinion as with the current R&TTE Directive.

Timeline (R&TTE to RED):



1.4 Overview of the services of Kiwa NL B.V.

1.4.1 Introduction of services

Kiwa offers four groups of services: Information, Certification, Test and Notified Body services.

The Information services of Kiwa as far as related to the RE Directive are:

- RED package (Project guidance)
- Storage of Technical documentation
- Compilation of a Technical File

The Test services of Kiwa relevant for the RE Directive are:

- Safety
- EMF (RF Safety)
- EMC
- Radio

The Certification services of Kiwa relevant for the RE Directive are:

- ISO 9000
- Compliance in Production
- EU-type examination (Module B) (Annex III RE)

The Notified Body services of Kiwa as defined by the RE Directive are:

- Approval of Quality Management System (Module H) (Annex IV RE)
- Surveillance

1.4.2 The RED Package (project guidance)

The RED Package (project guidance) is a service to assist the manufacturer or his authorized representative in his objective to meet all the requirements of the RE Directive for placing his product on the market. This is done by means of supplying information to the manufacturer. The complete process is managed by Kiwa and finally the manufacturer has to sign the documents (declarations) delivered to Kiwa.

Elements of the RED Package are:

- List containing all related mandatory and voluntary standards
- Marking/label
- Additions to manual
- Package instructions
- Proposal on declarations (need to be printed on company letter head paper!)
- Assistance with the central register of specified radio equipment
- Archiving of the Technical Documentation by Kiwa (as long as required by the RE Directive)
- Supplying information on current and changing regulations
- Granting access to surveillance authorities
- Delivering maintenance of the Technical Documentation in case of additions / modifications

Internal Production Control and voluntary certification of a Quality Management System are outside the scope of the RED Package. So are the costs involved with Testing and Notified Body activities.

1.4.3 Storage of technical documentation

The procedures of Kiwa regarding the archiving of files, which are part of the accredited quality system of Kiwa, are applicable for this storage of Technical Documentation.

1.4.4 Compilation of a Technical File

This is explained in Chapter 6.

1.4.5 Safety Testing

The essential requirement of article 3.1(a) of the RE Directive is about safety and health of persons and of domestic animals. It includes the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying.

Radio equipment falling within scope of this directive shall not be subject Low Voltage Directive (their chargers do need to comply with the LVD). However, the same electrical safety requirements as in the LVD apply, but without the limits set by the LVD.

All harmonized standards published under the LVD Directive can be used to obtain the pre-assumption of compliance with the requirements of the LVD. You can find a list of all European harmonized standards published under the LVD Directive in http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage/index_en.htm

Safety testing is available in the test laboratory of Kiwa. For the latest information see [Radio, Wireless and Electrical Equipment testing and certification. | Kiwa](#)

1.4.6 EMF (RF Safety) Testing

All products falling under the scope of the RE Directive have to be safe, see article 3.1(a). The European Commission published the following document to cover safety aspects:

- “Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)” (1999/519/EC). The document can be found at:
<https://osha.europa.eu/en/legislation/guidelines/council-recommendation-1999-519-ec-on-the-limitation-of-exposure-of-the-general-public-to-electromagnetic-fields-0-hz-to-300-ghz>.
- The occupational EMF directive 2004/40/EC can be found at:
<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004L0040>
- The amendment 2008/46/EC can be found at:
<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008L0046>
- There are harmonized standards available to cover the regulation (EN 50566, EN EN50360, EN62311 and EN 62479):
<http://www.cenelec.eu/>
- Standards to cover the directive:
<http://www.cenelec.eu/>

1.4.7 EMC Testing

The essential requirement of article 3.1(b) of the RE Directive is one on one linked to the EMC Directive (2014/30/EU).

All harmonized standards published under the EMC Directive can be used to obtain the pre-assumption of compliance with this essential requirement of the RE Directive. You can find a list of all European harmonized standards published under the EMC Directive in http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm

EMC testing is available in the Kiwa test laboratory. For the latest information with respect to:

- Radio products see [Radio, Wireless and Electrical Equipment testing and certification. | Kiwa](#)

1.4.8 Radio Testing

The essential requirement of article 3.2 of the RE Directive is about “effective use of the spectrum”.

All harmonized standards published under the RE Directive can be used to obtain the pre-assumption of compliance with the radio requirements of the RED. You can find a list of all European harmonized standards published under the RE Directive in http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/rte/index_en.htm

As you will see there are at the moment just a limited number of harmonized standards published under the RE Directive. The consequence is that for a lot of products using the radio spectrum there are no harmonized standards available. These standards are under development (at ETSI). Due to absence of applicable harmonized standards, manufacturers cannot use Annex II to prove compliance for some radio products. The only remaining alternatives for these products are Annex III and IV. In both remaining conformity assessment procedures Technical Documentation has to be created. The easiest way to realize technical documentation for the radio essential is to perform testing to an applicable national standard or applicable ETS/EN specification.

When ordering an Annex III EU-type examination (see Chapter 4.3), Kiwa will deliver a free of charge information service, supplying the manufacturer with the identification of the (non-harmonized) standards, which can be used for proving compliance to the radio essential requirements. It is essential for this service, that Kiwa has the correct product documentation (or accurate information about the product characteristics) at their disposal.

Radio testing is available in our laboratory. For the latest information see [Radio, Wireless and Electrical Equipment testing and certification. | Kiwa:](#)

EU-type examination (Module B)

EU-type examination is the part of a conformity assessment procedure in which Kiwa examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3 of the RED.

When Kiwa finds that the essential requirements or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that the manufacturer takes appropriate corrective measures and shall not issue an EU-type examination certificate.

When an EU-type examination was already issued and later it is found that the radio equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate if necessary.

1.4.9 Surveillance

Kiwa can be involved in market surveillance to trace if non-compliant radio equipment is available on the market. If so, Kiwa will inform and share this information with other notified bodies. Kiwa, as a Notified Body can perform market surveillance tests in its own test lab and has to inform the national market surveillance authority (Ministry of Economic Affairs - Agentschap Telecom) if there is any non-compliance.

1.5 Flow diagram of services

For the follow diagram of all Kiwa RED related services see figure 1.

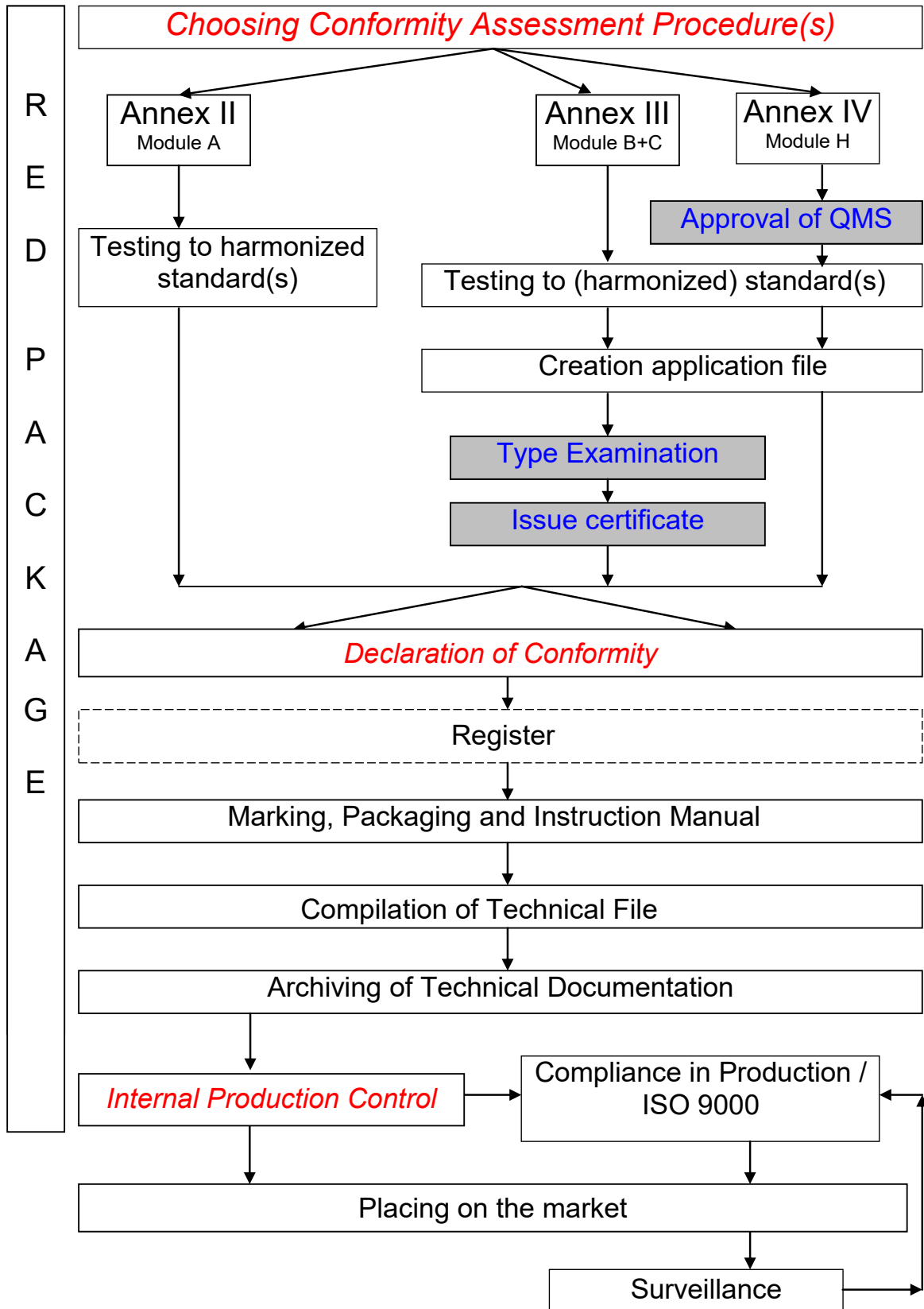


Figure 1: Flow diagram of services

Some clarification:

Some activities are the direct responsibility of the manufacturer: they cannot be subcontracted or outsourced to third parties. In the flow diagram these activities are described with *Italic letters and in red (Choosing Conformity Assessment Procedure, Declarations and Internal Production Control)*. The activities mentioned in gray boxes with blue letters have to be done by an RE Notified Body, like Kiwa. All the other activities can be fulfilled by the manufacturer or a third party. Kiwa -as a third party- can supply services for all these activities, except *Placing on the market*. Testing can be performed by Kiwa. In some cases (dependent of the availability or transportability of test equipment) the tests can also be performed on location. The *Creation of a Technical Documentation* is an activity of the manufacturer.

A new service in which Kiwa can assist is registering some radio equipment which show a low level of compliance with the essential requirements within a central system. This system has to be used as from 12 June 2018. The Commission will use delegated acts to specify which type of radio equipment needs to be registered.

2 European regulations

2.1 Introduction

The policy objectives of the first harmonization of EU Regulations and directives, concentrating on the elimination of trade barriers and on the free movement of goods for the development of a single market, are now being balanced out by a comprehensive policy geared to ensuring that only safe and compliant products find their way to the market, in such a manner that honest economic operators can benefit from a level playing field, thus promoting at the same time an effective protection of the EU consumer and a competitive single EU market.

Policy orientations and legislative techniques alike have profoundly changed in the last 35 years of European integration, especially in the area of the free movement of goods, contributing to make this area of activity a symbol of the success of the Single Market today.

Historically, EU legislation for goods has progressed through four main phases:

- the traditional approach or 'Old Approach' with detailed texts containing all the necessary technical and administrative requirements;
- the development of the 'New Approach' in 1985, which restricted the contents of legislation to the "essential requirements" leaving the technical details to European harmonised standards. This in turn led to the development of the European standardisation policy in support of this legislation;
- the development of the conformity assessment instruments made necessary by the implementation of the various Union harmonisation texts, both 'new approach' and 'old approach', leading to the 'Global approach' as described in Council Decision 93/465/EEC of 22 July 1993;
- the 'New Legislative Framework'¹ adopted in July 2008, which builds on the 'New Approach' and completes the overall legislative framework with all the necessary elements for effective conformity assessment, accreditation and market surveillance including the control of products from third countries.

¹ Regulation 765/2008 and Decision 768/2008/EC

2.2 The New Legislative Framework (NLF)

This is a general framework of a horizontal nature for future legislation harmonizing the conditions for the marketing of products and a reference text for existing legislation.

In the Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products², and repealing Council Decision 93/465/EEC provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures from which the legislator can select as appropriate. The Annex I of this document shows the different responsibilities of manufactures (Article R1), authorized representatives (Article R2), Importers (Article R4) and distributors (Article R5).

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products³ and repealing Regulation (EEC) No 339/93. This regulation lays down rules on the organization and operation of accreditation of conformity assessment bodies performing conformity assessment activities. It also provides a framework for the market surveillance of products to ensure that those products fulfill requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security and provides a framework for controls on products from third countries. This Regulation lays down the general principles of the CE marking.

[*Regulation \(EC\) No 764/2008 of the European Parliament and of the Council*](#) of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC. The aim of this Regulation is to strengthen the functioning of the internal market by improving the free movement of goods. This Regulation lays down the rules and procedures to be followed by the competent authorities of a Member State when taking or intending to take a decision, which would hinder the free movement of a product lawfully marketed in another Member State. It also provides for the establishment of Product Contact Points in the Member States to contribute to the achievement of the aim of this Regulation.

2.3 NLF and RED

The RED should take into account of the horizontal legal framework for the marketing of products in the internal market, established by Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products as well as by Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

2.3.1 Economic operators:

Four economic operators are defined: Manufactures, Authorized representatives Importers and Distributors. The economic operators have different obligations (a summary is given in table1), which are in line with the NLF (Decision No 768/2008/EC). Articles 10 – 13 of the RED mention the obligations of the economic operators.

² OJ L 218, 13.8.2008, p. 82

³ OJ L 218, 13.8.2008, p. 30

A new requirement of the RED is the mandate to provide more contact information for the economic operators. EU Member States will require the economic operators to include both website addresses and physical location postal addresses, in order to facilitate better communications between the member states, market surveillance authorities, economic operators, and consumers. The equipment must show the product identification numbers and contact information for the responsible parties. A contact name and details must be supplied with each device, and also placed on the device or in documentation if it is a small device. Importers must show similar information on the equipment or on the packaging; the supply chain must accept the legal responsibility for providing valid contact information. Importers will be seen as manufacturers when placing products under their own name, brand name or changing the equipment.

Economic operators shall, on request, identify the following to the market surveillance authorities:

- Any economic operator who has supplied them with the radio equipment.
- Any economic operator to whom they supplied radio equipment.

Economic operators shall be able to present this information for 10 years after they have been supplied with the radio equipment and for 10 years after they have supplied the radio equipment.

More summarising information about the obligations of Economic Operators can be found in table 1.

	Manufacturer	Authorised representative	Importer	Distributor
Design and manufactured conform essential requirements	YES			
Placing on the market only when comply to essential requirements	YES		YES	YES
Ensure radio equipment can operate in at least 1 member state	YES		YES	Verify
Carry out the relevant conformity assessment procedure	YES, or have it carried out		Ensure it is carried out	
Technical Documentation	Issue and 10 years filling and providing	Yes 10 years filling and providing	Ensure it is drawn up and 10 years filling and providing	Verify
DOC	Issue and 10 years filing	10 years filling and providing	10 years filling and providing	Verify
CE mark	Affix		Ensure	Verify
Type, serial number, id	On equipment (or package or documentation for very small equipment)		Ensure	Verify
Name, tradename or registered trade mark postal address	On equipment (or package or documentation for very small equipment)		Check details + add postal importer.	Verify details manuf. + importer
Manual + spectrum info and user restrictions.	Issue + add to equipment.		Ensure	Verify
Continuous compliance of series production	Have a procedure to ensure series production in compliance			
Corrective actions on Non-compliances	Corrective measures		Corrective measures	Corrective measures
Inform National authorities when risk.	YES		Yes+ manufacturer	Yes+ manufacturer
Cooperation National authorities	YES	YES	YES	YES
Cooperation National Authorities for market surveillance	YES + 10year	YES + 10year	YES + 10year	YES + 10year

Table 1: Economic operators and different aspects of the certification process

2.4 Implementation of the RED

The general objectives and main instruments of the R&TTE have not changed in the RED.

The RED is implemented in two phases:

- **Transition phase:** During transition R&TTE or RED can be used. Existing equipment can still be placed on the market (**until 13 June 2017**).
- **Operation phase:** Any new products placed on the market must be in compliance with the new Radio Equipment Directive (2014/53/EU), **starting on 12 June 2016**.

2.4.1 Transition provisions from R&TTE to RED

The new Directive 2014/53/EU can only be used **starting June 13, 2016**, and not before. There is a one-year transitional period between June 2016 and June 2017 where the new 2014/53/EU or old 1999/5/EC Directive can be used.

RED Article 48 'Transitional provisions' are as follows:

Member States shall not impede, for the aspects covered by this Directive, the making available on the market or putting into service of radio equipment covered by this Directive which is in conformity with the relevant Union harmonisation legislation applicable before 13 June 2016 and which was placed on the market before 13 June 2017.

2.4.2 Differences between R&TTE and RED

Some major changes of the new Radio Equipment Directive (RED) compared to the old R&TTE directive are:

- RED scope includes radio communication and also radio determination (RFID, radar, movement detect, etc.) equipment. Radio equipment not for communication or determination is not within the scope of the RED.
- RED only applies to wireless/radio products; wired Telecom Terminal Equipment (TTE) is not covered anymore. EMCD and LVD will apply to telecom equipment.
- Broadcast receivers now fall into the RED scope (they used to be in the EMC directive)
- No lower limit of the frequency range covered (in the R&TTE lower limit was 9 kHz), upper limit remains at 3000GHz.
- Notified Body number with CE mark may now only be used if the Quality System of the manufacturer was assessed against RED requirements by the Notified Body (Full Quality Assurance – Module H))
- Equipment class 2 notifications to national Authorities no longer required
- Class 2 labeling (Alert Sign) no longer required, but usage restrictions in certain member states must still be show on the package.
- CE mark in the user manual no longer required, but manual must show RF Band and transmitter power.

- Notified Body Opinion will be replaced by “EU-type examination Certificate”
- Evaluation kits are now excluded (no approval required under RED)
- RED requires that the use of universal chargers is made possible
- RX only (like GPS) devices remain in scope
- Manufacturer or Importer Address must be shown on device, or in user manual if device too small
- Safety requirements now explicitly apply also for animal related equipment (was in R&TTE but not clear)
- New products are introduced in the RED: Broadcast receivers and Inductive Data Transmission devices working at frequencies < 9kHz

2.5 Scope of RED

Telecommunications Terminal has been dropped from the title of the previous R&TTE Directive. This is because telecommunications terminal equipment, such as wired telephones and fax machines, has been removed from the scope of RED, and has been transferred to the scopes of the EMC Directive 2014/30/EU and Low Voltage Directive 2014/35/EU. RED will only apply to wireless and radio devices and equipment.

There is specific definition given for radio equipment in RED, which is “an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radio determination, or an electrical or electronic product which must be completed with an accessory, such as an antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio determination.” This definition is important in understanding the extent of the types of radio equipment to be covered under the scope of this directive.

The scope of RED will cover radio transmission, including both radio communication and radio determination. The term Radio Determination is used to make clear that equipment such as RADAR, RFID, movement detection, and velocity measurement are within the scope of RED. Equipment which is not for radio communication or determination is not in the scope, such as equipment classified for Industrial, Scientific, & Medical (ISM), EN 55011, and CISPR 11. Also in the scope will be radio reception equipment, including receive-only radio devices. One key change to the scope is the inclusion of broadcast receivers in RED, which were specifically excluded in R&TTE. Broadcast receivers had been in the scope of the EMC and Low Voltage Directives, but this will no longer be the case. Some items specifically excluded from the RED scope include aeronautical radio equipment, and custom evaluation kits intended for professional Research & Development, which are used in actual R&D facilities.

The frequency range of RED is expanded, up to 3 THz (3000 GHz), with no lower limit, meaning that zero Hertz to 9 kHz is now included in the scope. So any radio technologies that operate below 9 kHz now fall under this directive, and other standards bodies such as ETSI and ECO will have to catch up to this change in a standard update.

Excluded from the new Radio Equipment Directive are:

- Radio equipment used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations
- Marine equipment falling within the scope of Council Directive 96/98/EC
- Airborne products, parts and appliances falling within the scope of Article 3 of Regulation (EC) No 216/2008 of the European Parliament and of the Council –
- Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes

- Radio equipment exclusively used for activities concerning public security, defence, State security, including the economic well-being of the State in the case of activities pertaining to State security matters, and the activities of the State in the area of criminal law.

Radio equipment falling within scope of this directive shall not be subject to (2014/35/EU) Low Voltage Directive (their chargers do need to comply with the LVD). However, the same electrical safety requirements as in the LVD apply, but without the limits set by the LVD. In other words, Radio Equipment that use less than 50VAC or 75VDC still need to follow the electrical safety requirements of the directive.

2.5.1 Scope of radio transmission

Scope will include radio communication and also radio determination. That is equipment such as radar, RFID, movement detection, velocity measurement, etc. Equipment which is not for communication or determination is out of RE Directive scope. For example ISM, EN 55011, CISPR 11, etc.

2.5.2 Scope of radio reception

Receive only radio equipment is still in scope. Broadcast receivers are also still in scope. They were specifically excluded from R&TTE Directive. There may be a longer transition period for broadcast receivers. These will therefore no longer be in the scope of EMCD and LVD.

2.6 Essential requirements

Equipment within the scope of the RED must meet the essential requirements of both the Low Voltage Directive and the Electromagnetic Compatibility Directive. The Directive also requires equipment to be constructed for efficient use of the radio spectrum, and to avoid interference with terrestrial and orbital communications. Additional requirements are made for certain classes of equipment.

The essential requirements laid down in Directive 1999/5/EC for fixed-line terminal equipment are now appropriately covered by Directive 2014/35/EU. Therefore the RED will not apply to fixed-line terminal equipment.

In Article 3 of the RED the essential requirements for radio equipment are stated. Radio equipment that does meet the essential requirement will be given a statement of compliance. Compliance is a result from a conformity assessment (Article 17). A full list of the essential requirements can be found in Annex B of this document.

2.7 Register

As from 12 June 2018, manufacturers shall register radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements within a central system (Article 5). The specific radio equipment will be determined by the European Commission by delegated acts.

2.8 Conformity assessment

All items of equipment within the RED scope, placed on the European market for the first time must follow one of the conformity assessment procedures.

Conformity assessment means the process demonstrating whether the essential requirements (as mentioned in Article 3) relating to radio equipment have been fulfilled. So compliance is against Essential requirements, not standards. However radio equipment which is in conformity with harmonised standards shall be presumed to be in conformity with the

essential requirements. There does not need to be a harmonised standard to apply one of the Conformity Assessment Procedures. The Essential Requirements apply even in the absence of harmonised standards.

The manufacturer shall perform a conformity assessment of the radio equipment before putting his equipment on the European market. In order to be legally used in the European market, equipment must comply with the requirements of the Directive.

In Article 17 of the RED the conformity assessment procedures are explained. The manufacturer can use either internal production control, assessment of technical documentation by a Notified Body (EU-type examination) or full quality assurance approval.

The conformity assessment shall take into account all intended operating conditions and, for the article 3(1)(a) essential requirement (Health & safety). The assessment shall also take into account the reasonably foreseeable conditions. Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirement in all possible configurations.

2.9 Bodies involved in the conformity assessment

A conformity assessment body is the body that performs conformity assessment activities. Conformity assessment bodies can get notified by their national notifying authority, according article 30 of the RED. To get notified the conformity assessment body needs to fulfil the requirements laid down in article 26 of the RED. The conformity assessment body is then notified to the European Commission and the other Member States of the EEA and thereby acquires the status of 'Notified Body'. After successful notification a conformity assessment body will have its own Notified Body identification number assigned by the Commission.

A Notified Body is a third party who is authorised to perform the tasks relating to conformity assessment as specified in any European Directive they are notified for. Hence it is possible a single Notified Body is notified for multiple fields of profession. The Notified Bodies designated by member state notifying authorities have to satisfy certain criteria regarding proficiency, independence, impartiality, etc. In this respect, standards like ISO/IEC 17020, ISO/IEC 17025, ISO/IEC 17065 are particularly important.

Although responsibility for conformity assessment lies entirely with the manufacturer, the RED makes it obligatory to enlist the services of a third party for module B+C or module H. The bodies involved in the conformity assessment have their own tasks and responsibilities.

Regarding to the RED the following bodies are defined:

- (1) Notified body
- (2) Testing laboratory

2.9.1 Notified Body

A list of Notified Bodies notified under the RED by the Member States to the European Commission can be found on Nando.

Enter in the last field (named: Keyword on Bodies Function) of the link:

<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=search.main>

“Certification” and push the Search button. A list of all Certification Bodies will be listed. Under number 0063 Kiwa is listed. Kiwa is a RED Product Certification Body. The products to be certified shall be subject to conformity assessment procedures of EU-type examination and production quality control.

2.9.2 Testing Laboratory

A test laboratory should be capable of performing tests, which are part of some of the conformity assessment procedures. The laboratory can be chosen by the manufacturer. The test laboratory can be the own appropriate laboratory of the manufacturer, or any other test laboratory on his behalf and under his responsibility. A test laboratory can be accredited on the basis of an assessment in accordance with a quality standard, i.e. IEC/ISO 17025. There is no legal obligation to use an accredited laboratory. Manufacturers are taking aspects like quality, policy, liability, procurement requirements, costs, etc. into account determining whether tests are outsourced and to whom. The test laboratory of Kiwa is accredited to IEC/ISO 17025.

2.10 Notified body obligations

Regarding article 34 & 36 of the RED there are some operational and information obligations of notified bodies. These obligations will be discussed in this section.

2.10.1 Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III and IV.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the radio equipment technology in question and the mass or serial nature of the production process. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the radio equipment with this Directive.
3. Where a notified body finds that the essential requirements set out in Article 3 or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue an EU-type examination certificate or a quality system approval.
4. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, a notified body finds that radio equipment no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the EU-type examination certificate or the quality system approval if necessary.
5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EU-type examination certificates or quality system approvals, as appropriate.

2.10.2 The information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or a quality system approval in accordance with the requirements of Annexes III and IV;
 - (b) any circumstances affecting the scope of or conditions for notification;
 - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting
2. Notified bodies shall, in accordance with the requirements of Annexes III and IV, provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same categories of radio equipment with relevant information on

issues relating to negative and, on request, positive conformity assessment results.

3. Notified bodies shall fulfil information obligations under Annexes III and IV

2.11 Coordination of notified bodies: REDCA and EUANB

According to article 38 of the RED notified bodies are obliged to take part in sectoral notified body groups. In the sectors radio and EMC, the applicable notified body groups are:

- Radio Equipment Directive Compliance Association (REDCA)
- European Union Association of EMC Notified Bodies (EUANB)

Kiwa has joined these groups and has actively contributed in these groups since its founding. Kiwa will continue contribution in these groups in future.

Kiwa follows Technical Guidance Notes (TGN's) and Reference documents (REFDOC's) officially issued by these notified body groups. TGN's are publicly available on the website of the REDCA (<http://redca.eu/>). REFDOC's are only shared between the member notified bodies.

3 Conformity assessment procedures

3.1 Overview

To prove as manufacturer your product complies with the essential requirements of the RE Directive you can use among three different conformity assessment procedures:

- **Module A – Internal Production Control**
No Notified Body involvement, a self declaration procedure. (DoC based on harmonised standards for all Essential Requirements 3.1, 3.2 and 3.3)
- **Module B+C – EU-type examination and Conformity to Type based on Internal Production Control**
Notified Body involvement to assess the technical documentation. Procedure can be followed when there is compliance to harmonized and NON-harmonized standards. (NO placing of NB number is allowed)
- **Module H – Full Quality Assurance**
Notified Body involvement to assess design, manufacturing, inspection and test processes. (Placing of NB number after CE Logo)

To demonstrate compliance of the radio equipment with the essential requirements set out in Article 3.1 of the RED, all three conformity assessment procedures can be used. The full text of the conformity assessment modules can be found in the annex II, III and IV of the RED and in annex C of this document.

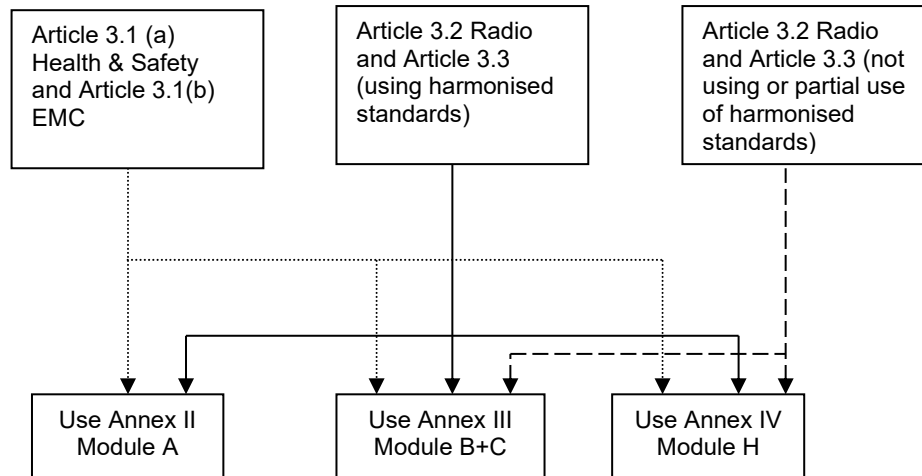
If to demonstrate the compliance of the radio equipment to Article 3.2 and 3.3 of the RED by using harmonised standards, than the choice is also all three conformity assessment procedures.

On the other hand if the manufacturer has not applied harmonised standards or only in part, or if such harmonised standards do not exist, then only RED Annex III Module B+C and RED Annex IV Module H can be used.

The choice of the conformity assessment procedure and all their aspects is an item of Kiwa's "RED Package". See chapter 1 for a description of the "RED Package".

In the next figure a flowchart is given.

Conformity Assessment Procedure



- (*) When Harmonised Standard(s) are applied to prove your product meets an essential requirement you are allowed to use Annex III Module C, although this is not obliged. Some manufacturers like to have the voluntary involvement of a third party with a respectable expertise of the RE Directive to verify their work. The EU-type examination as defined in Annex III Module C is an effective solution for this demand.

Figure 2: Choices of Conformity Assessment Procedures

There are in total 12 essential requirements defined by the Directive (see Annex B). Three of them are always applicable (Safety, Electromagnetic Compatibility and Effective use of the spectrum). One of them (Effective use of the spectrum) is only relevant when the product is an intended radiator (a radio transmitter). For the other 9 essential requirements, the Commission shall adopt delegated acts according article 44 of the RED, to specify for which categories or classes of radio equipment they are applicable.

Manufacturers are allowed to use a separate conformity assessment procedure for every essential requirement (within the restrictions given in the flow chart above).

Ultimately – regardless the choice of the conformity assessment procedure - the manufacturer has to draw up and sign a Declaration of Conformity, with reference to all applicable essential requirements.

Below is a table which shows when a Notified Body is needed when using or not using harmonized standards for the essential requirements.

Essential requirements	Use of harmonized standards	Use of non-harmonized standards
3.1.a protection health, safety	NB not mandatory	NB not mandatory
3.1.b EMC	NB not mandatory	NB not mandatory
3.2. Efficient use of radio Spectrum	NB not mandatory	NB mandatory
3.3a Interworks with accessories	NB not mandatory	NB mandatory
3.3b Interworks via networks	NB not mandatory	NB mandatory
3.3c Can be connected to interfaces of appropriate type	NB not mandatory	NB mandatory
3.3.d No harm to network	NB not mandatory	NB mandatory
3.3.e Safeguarding personal data and privacy.	NB not mandatory	NB mandatory
3.3.f Protection from fraud.	NB not mandatory	NB mandatory
3.3.g Access to emergency services	NB not mandatory	NB mandatory
3.3.h Facilitate users disability	NB not mandatory	NB mandatory
3.3.i. Only Compliant software can be loaded.	NB not mandatory	NB mandatory

Table 2: Essential requirements of the RED.

3.2 The Kiwa Approach and the RE Directive

The NLF which is the basis for almost all the European Directives with respect to product compliance describes procedures for the assessment of products. Each procedure comprises both the design phase and production phase of a product. The procedures differ in nature and are applied according to the potential risk associated with a non-compliance product. For instance, pacemakers have to satisfy much more stringent assessment requirements than toy trains.

Depending on the risk associated with a particular product, Directives specify in which cases the manufacturer himself may determine whether the products conform to the essential requirements in the Directive(s) and in which cases this has to be assessed by a third party, a *Notified Body*, by means of certification.

Kiwa as a Notified Body has developed the Kiwa Approach, which is a superset of the Radio Equipment Directive requirements. The Kiwa approach can also be used for approval scheme outside Europe and for voluntary product certification.

3.3 Testing, certification and notified body services of Kiwa in relation to the RED conformity assessment procedures.

The Notified Body services of Kiwa were earlier briefly described in the chapter 1. The Kiwa approach to conformity assessment comprises of testing, certification services and other notified body services, which will be described in relation to the different modules of conformity assessment in this section.

3.3.1 Internal production control with regard to Annex II Module A

Conformity assessment procedure Module A comes down to the manufacturer having to assess both the design and production of his products himself. Technical documentation must be prepared by the manufacturer in accordance with article 21 of the RED. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance with the technical documentation and with the essential requirements of the RED. Then the CE marking shall be affixed to each item that satisfies the applicable requirement of the RED. Also a DoC (Declaration of Conformity) shall be written for each radio equipment type. It's a self-declaration procedure and the application of Notified Body service is not mandatory. However Testing services by Kiwa or ISO 9000 service might be requested by the manufacturer on a voluntary basis.

3.3.2 EU-type examination + Conformity to Type Based on Internal Production Control with regard to Annex III Module B+C

For the conformity assessment procedure B+C the manufacturer assesses both the design and production of his products himself. In addition to that the manufacturer has to perform specific radio tests. In case those radio tests are not defined by Harmonised Standards, Kiwa defines applicable test methods. Kiwa must check if all selected/defined tests have been carried out and that compliance with the essential requirements is established.

The manufacturer starts with preparing the technical documentation in accordance with article 21 of the RED. Then the manufacturer submits his application Kiwa.

Module B (EU-type examination)

Kiwa examines the technical documentation and supporting evidence to assess compliance with the RED and writes an evaluation report. Only if the equipment is found to be compliant, the notified body issues an "EU-type examination Certificate". See section 4.3 how Kiwa issues the EU-type examination certificate.

The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly (see Chapter 5 for more details).

The manufacturer must inform Kiwa of all modifications to the product that may affect compliance with the essential requirements or the conditions for validity of the EU-type examination certificate. Chapter 5 describes how a manufacturer can apply with Kiwa for these kind of changes.

Kiwa shall inform its notifying authority and other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn.

If harmonised standards have not (or not fully) been applied on an issued EU-type examination certificate and/or additions thereto, Kiwa must inform the Member States.

Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by Kiwa. Kiwa shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for at least 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

Module C (Conformity to type base no internal production control)

The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of the RED.

After that the CE marking shall be affixed and a DoC shall be written to each item which satisfies the applicable requirements of the RED. The manufacturer must operate approved processes for design, manufacture and final testing.

3.3.3 Full Quality Assurance with regard to Annex IV Module H

Full quality assurance (FQA) is an approval of the manufacturer's processes which permits the application of the Notified body number to products within the scope of the full quality assurance. It works as follows: The manufacturer submits an FQA application to a single notified body of his choice which includes a sample set of technical documentation for each product type. The quality system must ensure compliance of the radio equipment with the requirements of the Directive 2014/53/EU (in accordance Annex IV of Module H), e.g. The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned. Also the processes must ensure compliance of the products. Manufacturer shall lodge an application for the assessment of his quality system with a Notified Body. And must allow a Notified Body access to audit design, manufacture, inspection, test and storage areas and provide necessary information on the quality system records. Quality systems based upon ISO 9001 and test facilities operating to ISO17025 inherently meet many but not necessarily all of the requirements for FQA Approval under the RED, see also Annex C (Module H) of this document. Kiwa is however not accredited to perform the Module H (RED) audit(s).

4 The application Product certification

4.1 Required documentation

The (technical) documentation to be submitted with the application must contain the information necessary to assess the product, such as:

- Signed Application form
- Signed Letter of Authorization
- Signed declaration that the same application has not been lodged with any other notified body
- Signed declaration that product will be used in minimal 1 member state
- Technical documentation according annex V of the RED (see annex D of this document)

The exact required documentation is indicated in the quick reference guide RX_061.

Kiwa will guide the client by using the documentation and test results to ascertain whether the equipment satisfies all the requirements. When this is the case an EU-type examination certificate can be issued out.

4.2 Product variants

A product may be marketed in different variations, however all of these variations need to be assessed by Kiwa. OEM products and product variants can be added to an EU-type examination if they comply with the following conditions.

Product

A product is equipment that is unique in its construction.

OEM product

One may market the same product under different type designations and/or trademarks. The products are 100% identical, in construction, hardware, software and physical outlining (OEM = Original Equipment Manufacturer).

Kiwa has defined two variant categories:

Product variants category one

These are products that are almost identical; however differ in some small details. Products that fall under this category are for instance the so-called stripped versions, etc.

Product variants category two

Products that are identical at large but differ that much that they do not fall under category one, will fall under category two. Examples of these products are: a different PCB layout is used while the electronic design is the same; different options are added to the same basic product, etc

4.3 The EU-type examination certificate

For the conformity route concerning Module B+C, as described in section 3.1 **Error! Reference s** **ource not found.** a EU-type examination will be issued. It contains:

- the name and address of the manufacturer and the certificate holder
- the applied standard and data to identify the equipment
- the conclusions of the examination
- the aspects of the essential requirements covered by the examination
- the conditions (if any) for its validity and the necessary data for identification of the assessed type.

The certificate holder can be either the manufacturer, authorized representative of the manufacturer or the importer.

The annexes accompanying the certificate contain information on the technical specifications on the basis of which the EU-type examination was issued and any conditions for its validity. This certificate is not transferable without the intervention of Kiwa. See also chapter 5 '*Modifications following certification*'.

The manufacturer is obliged to keep the technical documentation and the EU-type examination and any follow-up certificates for at least 10 years after the last product has been placed on the market. See also chapter 6 '*The technical file*'.

Annex G1 shows an example.

4.4 Follow-up to the EU-type examination certificate

Products are often modified (can be initiated by customer or notified body) after it has been certified. In such cases, it is often unnecessary to test all the equipment again; an additional verification and inspection will suffice. See also chapter 5 '*Modifications following approval*'. Where necessary, Kiwa will issue a follow-up to the EU-type examination.

4.5 General requirements to issue a EU-type examination

This section describes 'The Declaration of Conformity', 'The technical file' and 'The affixing of marking' requirements that do apply to all aforementioned procedures.

4.5.1 The Declaration of Conformity

The manufacturer must draw up a *Declaration of Conformity (DoC)* for each type of equipment. This is a document in which the manufacturer or importer declares that the product in question is in compliance with the Directive 2014/53/EU (RED).

The manufacturer shall state that the fulfilment of the essential requirements set out in Article 3 has been demonstrated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed.

A model of the Declaration of Conformity is given in annex VI of the RED and a copy of that can be found in Annex E of this document.

More Directives can be mentioned on 1 DoC (article 18).

The content of the DoC (Annex E of this document):

- Radio Equipment (product, type, batch, serial)
- Name, address of manufacturer or is authorised rep.
- Declaration conformity is issued under sole responsibility of manufacturer.
- Object of declaration (for traceability).
- Is in conformity with 2014/53/EU (you should not mention LVD/EMC).
- Description accessories and components.
- Reference to the harmonised standards.
- Where applicable NB number and issued EC type certificate number.
- Signing, date, place of issue.

The Simplified DoC

Radio equipment need to be accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. The possibility of using the simplified DoC according annex VII makes the process easier to show compliance to the RED. The simplified DoC needs to be continuously updated. It shall be translated into the language or languages required by the Member State in which the radio equipment is placed. The full text of the EU declaration of conformity shall be available at the internet address referred to in the simplified EU declaration of conformity.

4.5.2 The Technical File

The manufacturer must compile a technical file. The manufacturer or his authorised representative in the EEA should keep this file for at least 10 years after the last product has been manufactured. If the manufacturer is not established in the EEA and has not appointed a representative, the file must be kept by the person who has placed the product on the market. The file is primarily intended for inspections carried out by competent national government authorities. See also chapter *The Technical File*.

4.5.3 The affixing of markings

The RED states that a CE marking consisting of the initials CE must be affixed to every product placed on the market of the EEA in accordance with all the provisions of these Directives (see also the section '*Markings*'). The CE logo only needs to be affixed once, even if several Directives apply. But the CE marking shall also be affixed onto the packaging.

4.6 Record of complaints

The certificate holder (manufacturer, authorized representative or importer) shall keep a record of all complaints and remedial actions relative to the products covered by any certificate granted by Kiwa and to make these records available to the certification body when requested. This record shall be part of the technical file. See also chapter '*The Technical File*'.

In case such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification, appropriate action should be taken. The certificate holder should document the actions.

4.7 Termination (expiration), reduction, suspension and withdrawal of Certificates

The certificates issued by Kiwa under ISO/IEC 17065 accreditation can get a change in their active status, as published on the Kiwa website, due to passing the expiry date, changes in the prerequisites for certification, when a non-conformity with the certification requirements is substantiated or when the client requests for changes. In RQ_160 is defined for the related possibilities e.g. termination, suspension and reduction which action must be taken and how these actions have to be performed.

According article 36 of the RED the notified body is obliged to report to the notifying authority of any restriction, suspension or withdrawal of certificates.

4.8 Appeal against decisions of notified body

According article 35 Member States shall ensure that an appeal procedure against NB decisions (like restriction, suspension and withdrawal of certificates) is available.

4.9 Maintenance of certificates

The issued EU-type examination certificates will be kept permanently in archived digital records. Along with the certificate all used technical documentation, declarations and reports will be stored permanently.

- 1) All issued EU-type examination certificates will be added to the publication list on the Kiwa website: [Search radio, wireless and electrical equipment certificates \(kiwa.com\)](https://www.kiwa.com/en/search-radio-wireless-and-electrical-equipment-certificates)

Kiwa has the obligation to keep any issued EU-type examination to the state of art, the notified body shall inform the manufacturer accordingly. See Chapter 5 how to perform this obligation.

A change with the R&TTE is that surveillance authorities are more soon authorized to withdraw products from the market if found that the product is not complying to the requirements and the economic operator is not taking adequate corrective actions within the timeframe given.

5 Modifications following certification

5.1 Types of modifications

One or more of the following types of modifications may be involved.

Modifications of an administrative nature:

- changes to the details of the certificate holder and or manufacturer;
- change of certificate holder and or manufacturer;
- alteration/addition of a type designation and/or trademark.

Modifications of a technical nature:

- addition of new product variants;
- modification of product hardware/software;
- modifications due to changing requirements;
- modifications not affecting the requirements.

5.2 Changes to the details of the certificate holder and or manufacturer

In this case, the certificate holder and or manufacturer remains the same, but there are changes, for example, to the address, fax number or telephone number. The certificate holder and or manufacturer should inform Kiwa of the changes as quickly as possible.

Comments

Modification does not affect the conformity. Kiwa will record the new details and send the applicant a confirmation. Certificates already issued remain unchanged or can be updated on request.

5.3 Change of certificate holder and or manufacturer

5.3.1 Change of the certificate holder

The EU-type examination Certificate is drawn up in the name of the certificate holder and is not transferable without the intervention of Kiwa. The name of the certificate holder can, however, be changed, in which case the new certificate holder automatically assumes all the responsibilities and obligations applicable under the issued EU-type examination in question.

Comments

The original holder of the certificate(s) must notify Kiwa in writing that the product should be transferred to the name of the new certificate-holder.⁴ All the type designations and certificate numbers to which the transfer applies should be listed.

The new holder of the certificate(s) should inform Kiwa in writing that he is taking over the EU-type examination or Certificate in question, and should list all the types and certificate numbers. He should also declare, and if necessary demonstrate, that he will fulfil all the responsibilities and obligations applicable under the original type-examination. The new certificate holder draws up a Declaration of conformity for each type and sends a copy to Kiwa.

4 If the holder has been declared bankrupt, the receiver is the approval-holder.

Kiwa will issue an *Follow-up to the EU-type examination*, in which the details of the new certificate holder are stated.

5.3.2 Change of the manufacturer

The EU-type examination shows the name of the manufacturer and is not transferable without the intervention of Kiwa. The name of the certificate holder can be changed after performing a new factory inspection to cover the FPC requirements.

Kiwa will issue an *Follow-up to the EU-type examination*, in which the details of the new manufacturer are stated.

5.4 Alteration/addition of a type designation and/or trademark

Alteration/addition of a type designation and/or trademark means that the hardware or software remains unchanged but the type designation and/or trademark under which the product is marketed is replaced by, or extended with, a new type designation.

Comments

In this case, the old type designation and/or trademark, is replaced by a new one. It is also possible to market a product under both the old and new type designation and/or trademark. This applies to OEM products.

The certificate holder should notify Kiwa in writing of the alteration or addition of the type designation and/or trademark and declare that the new type(s) are identical to the already approved type. He should also indicate the old type designation and/or trademark and the approval/registration number and new type designation and/or trademark.

A follow-up of the EU-type examination will be issued to the certificate holder. All the relevant type designations and/or trademarks are listed in an annex of this certificate.

5.5 Addition of new products variants

Addition of new product variants means that a new product variant is added to a type. The variants must all be based on the same design and may differ only in options, version, etc.

Comments

It is possible to place several product variants under one EU-type examination, each having its own type designation and/or trademark. However, the variants must form a product family, i.e. the variations in the products must be based on the same design. It must be possible to demonstrate that the variants belong to the same type, e.g. by means of a technical examination by a designated laboratory.

Kiwa issues a follow-up of the EU-type examination in which the relevant type designations and/or trademarks are listed

5.6 Modification of product hardware/software

This means that product hardware and/or software are modified in a way that affects, or may affect, conformity with the essential requirements.

Comments

The product must be subjected to (additional) tests by a designated laboratory. The additional test report(s) and all other altered documentation are submitted to Kiwa together with a modification application.

Kiwa issues a follow-up of the EU-type examination.

5.7 Modifications due to changing requirements

As described in section 3.3.2 and 4.9 Kiwa needs to perform some maintenance on issued EU-type examinations.

Kiwa will have a new system designed that allows for an automatic pick of certificates which are about to expire or need to comply on changes of standards/rules. The manufacturer will be informed on time to take adequate action.

5.8 Modifications not affecting the requirements

Technical, editorial and cosmetic modifications made to products already certified that will not affect conformity with the requirements as defined in the harmonised standard, AND if address details of the manufacturer and certificate holder remain unchanged, AND if the product description, type designation, hardware/firmware/software versions remain unchanged, THEN it is not needed to notify (inform) Kiwa.

However, if any modification does affect one or more of the items mentioned, adequate information about the change(s) need to be provided to Kiwa. In case of any doubt Kiwa shall be informed about the case involved.

6 The Technical File

6.1 Introduction

The RED requires the manufacturer to compile a technical file. This file should contain all the technical documentation that can be used to show that the product complies with the requirements of the RED.

This section provides further information on the scope, content and form of the Technical File.

6.2 Purpose of the Technical File

The technical file plays a key role in the conformity assessment of a product. The manufacturer in co-operation with the approved bodies assesses the product and keeps the (test) data in a Technical File.

The file compiled by the manufacturer is primarily intended for the national authorities responsible for inspections. The national authorities have the right to require the manufacturer, its authorized representative or importer to provide data showing that a product satisfies the requirements of the RED. If the manufacturer, its authorized representative or importer is unable or unwilling to supply this data, this provides sufficient grounds for questioning the '*presumption of conformity*' with the RED or for imposing sanctions.

In the case of products under the scope of the RED, the Technical File is one of the elements for carrying out a conformity assessment with optionally the involvement of a third party (Notified Body). In such cases, the EU-type examination issued by a Notified Body also forms part of the Technical File.

6.3 Form and content of the Technical File

The specific information that should be included in the technical file depends on the nature of the product and on the technical details needed to demonstrate that it conforms to harmonised standards. This should be indicated on a case-by-case basis, depending on the product. It is recommended that the technical file shall be organized as follows:

- Technical documentation;
 - A general description of the product;
 - Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc;
 - Descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product;
 - A list of the standards referred to in Article 16, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where such standards referred to in Article 16 have not been applied or do not exist (Article 16 of the RE Directive 2014/53/EU);
 - Results of design calculations made, examinations carried out, etc.;
 - Test reports.
- EU-type examination;
- Declaration of Conformity;
- Category of product;
- Packaging information;
- An explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10).

Further details on the content of the technical file can be found in Annex V of the RED. In this report a copy can be found in Annex D.

6.4 Availability of the Technical File

The technical file should always be kept available to the national authorities for inspection purposes and to Kiwa. The obligation to have at least one Technical File available on the territory of the EEA commences when the product is placed on the market of the EEA, regardless of the product's geographical origin.

The obligation to keep the Technical File available rests with the manufacturer, his authorised representative and importer established in the European Union. The file should be kept for at least ten years after the date on which the product was placed on the market.

7 Markings

All radio products within the scope of the RED, for which harmonised standards exist, are subject to CE marking. The exact form and conditions are described in this section.

7.1 The CE marking

The affixing of a CE marking (Conformité Européenne) to products is an essential part of the NLF. With the CE marking the manufacturer indicates his responsibility for the product conformity with the essential requirements and its compliance with the RED and other European Union harmonisation legislation. If several Regulations or Directives apply, the CE marking may, as a rule, be affixed only to products that comply with the conditions of all these Regulations and Directives. When several Regulations or Directives apply, the initials CE need to be affixed to the product only once.

The CE marking must satisfy the following criteria:

- The CE conformity marking shall consist of the initials "CE " taking the following form:

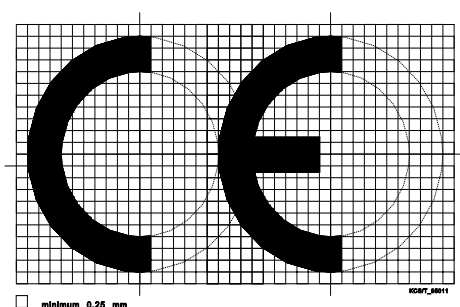


Figure 4: The initials CE.

- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- On account of the nature of radio equipment, the height of the CE marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.
- The CE mark shall be affixed visibly, legibly and indelibly to the radio product or to a label attached to it or, where this is not possible or not warranted due to the nature of the product, to the packaging or to the accompanying documents.
- The CE marking shall be affixed before the radio product is placed on the market.

Additionally the CE marking shall:

- Not be followed by the identification number of the notified body where the conformity assessment procedure set out in Annex III is applied, only when Annex IV (full quality assurance) is applied the NB number should be placed after the CE mark. The identification number of the notified body shall have the same height as the CE marking.

As soon as Kiwa in their function as RED Notified Body is involved in Annex IV of the conformity assessment procedures the marking will (at least) be as follows (currently not able to offer this service):




Figure 5: Example of the marking for the products when using Annex IV

In addition to this marking numbers of other Notified Bodies, which are involved in one of the conformity assessment procedures, have to be added.

The marking shall be affixed visibly, legibly and indelibly.

Equipment where the use of its spectrum allocation is not allowed in at least one Member State of Europe, it will be not allowed to make the product available on the EU market.

Not complying to this rule, means NO CE mark may be placed on the device as it does not comply to the Directive (European Commission).

Last note: the exclamation mark (!), as known under the former R&TTE is no longer allowed to be used.

7.2 Marking of registered radio equipment

Radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements are as described in Chapter 2.6 registered within a central system prior to being placed on the market. The Commission shall allocate to each registered radio equipment type a registration number, which manufacturers shall affix on radio equipment besides the CE marking.

Annex A, Abbreviations and paraphrases

Accredited laboratory

A laboratory operating in accordance with a quality standard -in this case ISO/IEC 17025- and which has been assessed by a recognised Accreditation Board.

Agentschap Telecom

Dutch Radiocommunications Agency

Specialised agency of the Ministry of Economic Affairs. The three main tasks of Radiocommunications Agency Netherlands are to obtain, allocate and protect frequency space.

Authorised representative

The person who, on the explicit (written) instructions of the manufacturer, acts on his behalf or for his account with respect to the obligations laid down by Law.

Category 1 or 2

The two categories products falling under the scope of the RE Directive. For category 2 products restrictions exists on its use.

CE

Conformité Européenne, French for European Conformity.

Certification

A procedure whereby a third party gives written assurance that a product, process or service conforms to specified requirements (ISO/IEC Guide 2: 1991).

Compliance in Production Scheme

A Kiwa defined certification scheme for ensuring continued compliance.

Conformity assessment

Systematic examination of the extent to which a product, process or service satisfies further specified requirements (ISO/IEC Guide 2: 1991).

DoC

Declaration of Conformity.

EA

European co-operation for Accreditation.

EEA

The European Economic Area (EEA) comprises the fifteen member states of the EU plus Norway, Liechtenstein and Iceland.

EMC

Electromagnetic Compatibility.

EMC Directive

This Directive (2014/30/EU) lays down the minimum requirements to be met by products, which may cause or be affected by electromagnetic disturbance.

EO

Economic operator

Family

A type may comprise several product variants in so far as the differences between them do not affect the safety level and the other performance requirements of the product. Several family variants of the product may be marketed. These family variants are all based on the same design, but the (host-dependent) options, version, etc. differ. The product variants form, as it were, a product family only then when in all possible configurations and/or versions at least one part for

connection to the public network has certain uniqueness. Family name refers to the totality of all possible (family) variants.

FQA

Full Quality Assurance.

Importer

Any person who places a product from a third country (defined as a country outside the EEA), on the market of the EEA.

Internal control of production

A conformity assessment procedure whereby the manufacturer assesses the design and production of his products himself.

ISO/IEC 17025

General requirements for the competence of testing and calibration laboratories is the main [ISO standard](#) used by testing and calibration laboratories.

ISO 9000

A group of international standards, comprising both quality management and quality assurance.

IT&T

Information Technology and Telecommunication.

LVD

Low Voltage Directive (Directive 2014/35/EU).

Manufacturer

The person responsible for the design and manufacturing of a product covered by a Directive with the view to place it on the market of the EEA on his own behalf.

MLA

Multilateral Recognition Agreement.

Notified Body

A Notified Body is a third party authorised to carry out the tasks relating to approvals described in a European Directive. In general, a Notified Body can be regarded as a competent approvals body in a field where approval (certification) of a product is compulsory by law. A Notified Body is designated by the State. A member state of the EEA (European Economic Area) can only designate bodies falling within its sphere of competence.

Bodies designated by a member state should satisfy criteria relating to proficiency, independence, impartiality, etc. In this connection, European standards ISO/IEC 17065 and ISO/IEC 17021-1 are particularly important. The body is then notified to the European Commission and the other member states of the EEA and thereby acquires the status of 'Notified Body'.

OEM products

A certificate holder may market the same product under different type designations and/or trademarks. One Statement is issued for the product in which all the relevant type designations and/or trademarks are listed. (OEM = Original Equipment Manufacturer.)

PQA

Production Quality Assurance.

QMS

Quality Management System.

RvA

Raad voor Accreditatie (The Dutch Council for Accreditation).

RE

Radio Equipment. Also RE Directive 2014/53/EU.

RE Compliant

A Kiwa defined certification scheme for products meeting the requirements of the RE Directive.

RED

Radio Equipment Directive

RED Package

A Compliance Management service of Kiwa.

Safety Directive

(73/23/EEC) Council Directive of 19 February 1973 on the harmonisation of the law of Member states relating to electrical equipment designed for use within certain voltage limits.

Standard

A standard is a technical specification drawn up by a recognised standards organisation (CEN, CENELEC or ETSI) for repeated or continuous application, but with which compliance is not necessarily compulsory.

Certificate holder

The person to whom a EU-type examination has been granted.

TCAM

Telecommunication Conformity Assessment and Market Surveillance Committee defined by article 13 of the R&TTE Directive.

TD

Technical Documentation

Technical specification

A technical specification is the specification contained in a document which lays down the characteristics required of a product such as quality levels, performance, safety, dimensions, including the requirements applicable to the product as regards terminology, symbols, tests and test methods, packaging, marking and labelling.

Kiwa

Certification services of Kiwa – Third party certification body accredited by The Dutch Council for Accreditation (Raad voor Accreditatie: RvA).

Trademark

Trademark refers to the generic (brand) name under which a product is marketed.

Type designation

Type designation refers to the unique name under which a product is marketed.

Type-examination

A procedure whereby a Notified Body assesses the design, possibly by means of tests, of a representative specimen of the production envisaged.

Annex B, Essential Requirements

In the next table all the (possible) essential requirements of the RE Directive are given.

The essential requirements of article 3.1 and 3.2 are always applicable. The essential requirements of article 3.3 are applicable to certain categories or classes of products falling under the scope of the RE Directive. The European Commission can make these essentials applicable for certain categories of products. For this reason the essential requirements of article 3.3 are called the possible essential requirements.

Article 3.1 item a	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.
Article 3.1 item b	An adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.
Article 3.2	Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.
Article 3.3 item a	The product shall be so constructed that it interworks with accessories, in particular with common chargers.
Article 3.3 item b	The product shall be so constructed that it interworks via networks with other radio equipment.
Article 3.3 item c	The product shall be so constructed that it can be connected to interfaces of the appropriate type throughout the Union.
Article 3.3 item d	The product shall be so constructed that it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service.
Article 3.3 item e	The product shall be so constructed that it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected.
Article 3.3 item f	The product shall be so constructed that it supports certain features ensuring protection from fraud.
Article 3.3 item g	The product shall be so constructed that it supports certain features ensuring access to emergency services
Article 3.3 item h	The product shall be so constructed that it supports certain features in order to facilitate its use by users with a disability
Article 3.3 item i	The product shall be so constructed that it 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

Annex C, RED Conformity assessment modules

CONFORMITY ASSESSMENT MODULE A

INTERNAL PRODUCTION CONTROL

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of this Annex, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the essential requirements set out in Article 3.

2. Technical documentation

The manufacturer shall establish the technical documentation in accordance with Article 21.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured radio equipment with the technical documentation referred to in point 2 of this Annex and with the relevant essential requirements set out in Article 3.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

CONFORMITY ASSESSMENT MODULES B AND C

EU-TYPE EXAMINATION AND CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

When reference is made to this Annex, the conformity assessment procedure shall follow Modules B (EU-type examination) and C (Conformity to type based on internal production control) of this Annex.

Module B

EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
 - (b) a written declaration that the same application has not been lodged with any other notified body;
 - (c) the technical documentation. The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the radio equipment. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;
 - (d) the supporting evidence for the adequacy of the technical design solution. That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied or have not been fully applied. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
4. The notified body shall examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the radio equipment.
 5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations as provided in

point 8, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive that apply to the radio equipment concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured radio equipment with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonized standards the references of which have been published in the *Official Journal of the European Union* have not been applied or not been fully applied. The Member States, the Commission and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for 10 years after the radio equipment has been assessed or until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Module C

Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the radio equipment concerned is in conformity with the type described in the EU-type examination certificate and satisfies the requirements of this Directive that apply to it.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to it.

3. CE marking and EU declaration of conformity

3.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 to each item of radio equipment that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

CONFORMITY ASSESSMENT MODULE H

CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the radio equipment concerned satisfies the requirements of this Directive that apply to it.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the radio equipment concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation shall contain, wherever applicable, the elements set out in Annex V;
- (c) the documentation concerning the quality system; and
- (d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the radio equipment with the requirements of this Directive that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programs, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality;
- (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonized standards will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met;

- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing radio equipment pertaining to the radio equipment type covered;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.;
- (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonized standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfill the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
 - (a) the quality system documentation;
 - (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
 - (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and EU declaration of conformity

- 5.1. The manufacturer shall affix the CE marking in accordance with Articles 19 and 20 and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each item of radio equipment that satisfies the applicable requirements set out in Article 3.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity shall identify the radio equipment type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the national authorities:
 - (a) the technical documentation referred to in point 3.1;
 - (b) the documentation concerning the quality system referred to in point 3.1;
 - (c) the change referred to in point 3.5, as approved;
 - (d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Annex D, Contents of technical documentation

The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the radio equipment including:
 - (i) photographs or illustrations showing external features, marking and internal layout;
 - (ii) (ii) versions of software or firmware affecting compliance with essential requirements;
 - (iii) (iii) user information and installation instructions;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) copy of the EU declaration of conformity;
- (f) where the conformity assessment module in Annex III has been applied, copy of the EU-type examination certificate and its annexes as delivered by the notified body involved;
- (g) results of design calculations made, examinations carried out, and other relevant similar elements;
- (h) test reports;
- (i) an explanation of the compliance with the requirement of Article 10(2) and of the inclusion or not of information on the packaging in accordance with Article 10(10).

Annex E, Declaration of conformity

1. Radio equipment (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the radio equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the radio equipment):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
 - Directive 2014/53/EU
 - Other Union harmonisation legislation where applicable
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared. References must be listed with their identification number and version and, where applicable, date of issue:
7. Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the EU-type examination certificate: ...
8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:
9. Additional information:
Signed for and on behalf of: ...
(place and date of issue):
(name, function) (signature):

Annex F, Forms and documents

General

Several forms and documents are available to assist you in applying for product certification. The list below covers the most important documents relevant to radio equipment.

RD_061 Conformity assessment procedures for the Radio Equipment scheme

RF_100 General Application Form

RQ_160 Termination (expiration), reduction, suspension and withdrawal of Certificates

Kiwa provide you with original copies of these forms (RF) and documents (RD), but you can also use photocopies or printouts obtained from our web-site. [Downloads - Kiwa W&E](#)

Annex G Format of EU-type examination certificate



CERTIFICATE

EU-type examination certificate (Module B)



<certificate number>



Issued	<date>	Date of expiration of validity <certificate number>
Page	<Page> of <NumPages>	

(This certificate has 1 page in Annexes.)

In compliance with the procedure specified in the **Radio Equipment Directive Scheme RD_061**, Kiwa Nederland B.V. declares as designated Notified Body 0063 for the Radio Equipment Directive, that the stated product complies with the essential requirements, in accordance with Article 3 of Directive 2014/53/EU and amending Directive (EU) 2022/2380, as indicated under Annex 1 of this certificate, based on the applicable technical standards and specifications as listed in Annex 2 of this certificate.

Product description:	<xxx>
Trademark:	<xxx>
Type designation:	<xxx>
Hardware / software:	<xxx> / <xxx>
Variants:	See Annex 3

This certificate is granted to manufacturer:

Name: <manufacturer>
Address:
City:
Country:

This certificate remains valid as long as the stated product stays in compliance with the essential requirements of the Radio Equipment Directive.

Kiwa Nederland B.V.



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7300 AC Apeldoorn
The Netherlands

<https://www.kiwa.com/nl/en/advies/radio-wireless-and-electrical-equipment/>

Chamber of commerce
08090048

Ron Scheepers
Managing director



Annex 1 to EU-type examination certificate

<certificate number>

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General Conditions

For each product to which this EU-type examination certificate relates, it has complied to the essential requirements as follows:

Article 3.1

Radio equipment shall be constructed so as to ensure:

CheckArt31a (a) 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;

CheckArt31b (b) an adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

Article 3.2

CheckArt32 Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

Article 3.3

Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:

- CheckArt33a (a) radio equipment interworks with accessories other than the charging devices for the categories or classes of radio equipment, specified in Part I of Annex 1a, which are specifically referred to in paragraph 4 of this Article
- CheckArt33b (b) radio equipment interworks via networks with other radio equipment;
- CheckArt33c (c) radio equipment can be connected to interfaces of the appropriate type throughout the Union;
- CheckArt33d (d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service;
- CheckArt33e (e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected;
- CheckArt33f (f) radio equipment supports certain features ensuring protection from fraud;
- CheckArt33g (g) radio equipment supports certain features ensuring access to emergency services;
- CheckArt33h (h) radio equipment supports certain features in order to facilitate its use by users with a disability;
- CheckArt33i (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.

Article 3.4

CheckArt34 Radio equipment falling within the categories or classes specified in Part I of Annex 1a shall be so constructed that it complies with the specifications relating to charging capabilities set out in that Annex for the relevant category or class of radio equipment.

Legend

C = Conform
NC = ~~Not~~ Conform
NA = Not applicable (for this product)
NP = Not performed (in this statement)

Annex 1 to EU-type examination certificate

<certificate number>

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- This EU-type examination certificate is limited to the Radio Equipment Directive.
- This EU-type examination certificate is part of the Conformity Assessment procedure Module B and C, as described in annex III of the Radio Equipment Directive.
- The validity of this EU-type examination certificate is limited to products, which are equal to the one(s) assessed for this EU-type Examination.
- When the manufacturer (or holder of this EU-type examination certificate) is placing the listed products on the European market or the countries of the EEA, he is obliged to label the products with the prescribed CE logo. The CE logo stands for conformity to all applicable Directives. Next to the CE logo the manufacturer has to draw up and issue a Declaration of Conformity, declaring that the product(s) described in this EU type-examination certificate, are in compliance with Directive 2014/53/EU and any other applicable EU harmonization legislation.
- Each product shall be identified by means of type, batch and/or serial numbers and the name of the manufacturer and/or importer.
- If the equipment is to be modified, Kiwa shall be notified immediately. Depending on the modifications, Kiwa may have additional examinations carried out in consultation with the applicant.
- Enforcement of a new amending directive voids the validity of this EU-type examination certificate.
- In case any referenced standard in this EU-type examination certificate is withdrawn or superseded and the presumption of conformity with the essential requirements has ceased, investigation by Kiwa is needed to determine the validity of this EU-type examination certificate.

Remarks and observations

The following conditions are applicable:

Annex 2 to EU-type examination certificate

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Documentation lodged for this EU-type examination certificate

Test Reports:

Product Documentation:

Technical Standards and Specifications

The product is compliant with:

Applied Standards



Annex 2 to EU-type examination certificate

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Technical features and characteristics

The product includes the following features and characteristics:

Annex 3 to EU-type examination certificate

<certificate number>

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The product as described in this certificate includes the following type designations:

Annex H, Additional information

For more information contact:

Kiwa B.V.

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