Conformity assessment procedures regarding Electromagnetic Compatibility Scheme

RD_030, Issue 14

This guide describes the conformity assessment procedures and requirements regarding EMC for products to be placed on the European, Japanese or USA market

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Function : Quality manager
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Verified by : Willem Jan Jong
Function : Manager Product Certification
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Function : Quality assurance manager
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1 Introduction

1.1 About the unit Wireless & EMC (Kiwa)

Kiwa Nederland B.V. (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 manufacturers, their authorized representatives, importers and distributors who want to place equipment on the European, Japanese and USA market. The European market is defined as the European Economic Area (EEA).

Described are the conformity assessment procedures regarding Electromagnetic Compatibility (EMC) that have to be followed before equipment may be placed on the market and how to act when modifications to such equipment are made. It also describes specific conditions, such as markings, Declarations of conformity, etc., which manufacturers and importers will have to deal with.

The conformity assessment procedures for Europe are derived from the European Directives and Regulations with EMC requirements. There is one general applicable EMC Directive 2014/30/EU (EMCD). Some products are excluded from the scope of the EMC Directive. In such cases the EMC requirements are defined in Directives applicable for the products involved (like 2014/53/EU for radio equipment).

The conformity assessment procedures for Japan are derived from the Japanese Radio Law.

The conformity assessment procedures for the USA are derived from 47 CFR Part 15B.

1.3 The Transition from old EMCD to new EMCD

The old EMC Directive 2004/108/EC will be withdrawn and cancelled on 20 April 2016, and the new European EMC Directive (EMCD) 2014/30/EU will become mandatory on the same date 20 April 2016.

The EMCD has been published in the Official Journal of the European Commission on 22 May 2014. The new EMCD has entered into force on 12 June 2014. From 20 April 2016, all member states must apply the new EMCD.

The repeal date for the old EMCD 2004/108/EC is 20 April 2016, and products compliant to the old Directive cannot be placed on the market anymore. All equipment placed on the market as from 20 April 2016, will need to meet the requirements of the new EMCD 2014/30/EU.

Under the new EMCD, Notified Bodies (NBs) will issue an EU-type examination Certificate instead of a Statement of Opinion.

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.

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 products, 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 R2), authorized representatives (Article R3), 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 products 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 fulfil 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.

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

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 EMCD

The EMCD 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 7 ~ 10 of the EMCD mention the obligations of the economic operators.

A new requirement of the EMCD 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 summarizing 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
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 and info about 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+ manufactur er	Yes+ manufactur er
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 new EMCD

The general objectives and main instruments and essential requirements have not changed between the old EMCD (2004/108/EC) and the new EMCD (2014/30/EU). Hence, the new EMCD is implemented directly on one single transition date 20 April 2016.

2.4.1 Transition provisions from 2004/108/EC to 2014/30/EU

According Article 43 the 'Transitional provisions' are as follows:

Member States shall not impede, the making available on the market and/or putting into service of equipment covered by Directive2004/108/EC which is in conformity with that Directive and placed on the market before 20 April 2016.

2.4.2 Differences between new and old EMCD

Some changes of the new EMCD compared to the old EMCD are:

- EMCD will apply to wired Telecom Terminal Equipment (TTE) equipment. It has been removed from the scope of the Radio Equipment Directive (RED).
- Broadcast receivers will be removed from the scope of the EMCD and now fall into the RED scope.
- CE mark in the user manual no longer required.
- Notified Body Opinion will be replaced by "EU-type examination Certificate"
- Manufacturer or Importer Address must be shown on device, or in user manual if device too small.

2.5 Scope of EMCD

2.5.1 Covered scope of equipment

The EMCD applies to *equipment* which means any apparatus or fixed installation.

Apparatus means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance.

Fixed installation means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location.

2.5.2 Exclusions from EMCD scope

The EMCD shall not apply to:
(a) equipment covered by Directive 2014/53/EU;

(b) aeronautical products, parts and appliances as referred to in Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC;

(c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union[2], unless the equipment is made available on the market;

(d) equipment the inherent nature of the physical characteristics of which is such that:
(i) it is incapable of generating or contributing to electromagnetic
emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
(ii) it operates without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use;

(e) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

For the purposes of point (c) above, kits of components to be assembled by radio amateurs and equipment made available on the market and modified by and for the use of radio amateurs are not regarded as equipment made available on the market.

2.6 Essential requirements

2.6.1 General requirements

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

2.6.2 Specific requirements for fixed installations

Installation and intended use of components

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the essential requirements set out in 2.6.1.

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[2] Constitution and Convention of the International Telecommunication Union adopted by the Additional Plenipotentiary Conference (Geneva, 1992) as amended by the Plenipotentiary Conference (Kyoto, 1994).

2.7 Conformity assessment

All items of equipment within the EMCD 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 6 of the EMCD) relating to 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 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 14 of the EMCD the conformity assessment procedures are explained. The manufacturer can use either internal production control or assessment of technical documentation by a Notified Body (EU-type examination).

The conformity assessment shall take into account all intended operating conditions. Where the equipment is capable of taking different configurations, the conformity assessment shall confirm whether the equipment meets the essential requirement in all possible configurations.

2.8 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 28 of the EMCD. To get notified the conformity assessment body needs to fulfil the requirements laid down in article 24 of the EMCD. 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 EMCD makes it possible to enlist the services of a third party for module B+C. The bodies involved in the conformity assessment have their own tasks and responsibilities.

Regarding to the EMCD the following bodies are defined:

(1) Notified body
(2) Testing laboratory

2.8.1 Notified Body

A list of Notified Bodies notified under the EMCD by the Member States to the European Commission can be found on Nando.
https://ec.europa.eu/growth/tools-databases/nando/
A list of all Certification Bodies will be listed. Under number 0063 Kiwa is listed. Kiwa is a EMCD Product Certification Body. The products to be certified shall be subject to conformity assessment procedures of EU-type examination.

2.8.2 Testing Laboratory

A test laboratory should capable to perform 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.

2.9 Notified body obligations

Regarding article 32 & 34 of the EMCD there are some operational and information obligations of notified bodies. These obligations will be discussed in this section.

2.9.1 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.
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 6 of the EMCD 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.
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.

2.9.2 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 in accordance with the requirements of Annexes III;
   (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, 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.

2.10 Coordination of notified bodies: EUANB

According article 36 of the EMCD notified bodies are obliged to take part in sectoral notified body group. In the sector EMC, the applicable notified body group is:

- European Union Association of EMC Notified Bodies (EUANB)

Kiwa has joined this group and has actively contributed in this group since its founding. Kiwa will continue contribution in this group in future.

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

2.11 EMC Conformity assessment procedures

2.11.1 Overview and flow diagram

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

- **Module A – Internal Production Control**

- **Module B+C – EU-type examination and Conformity to Type based on Internal Production Control**

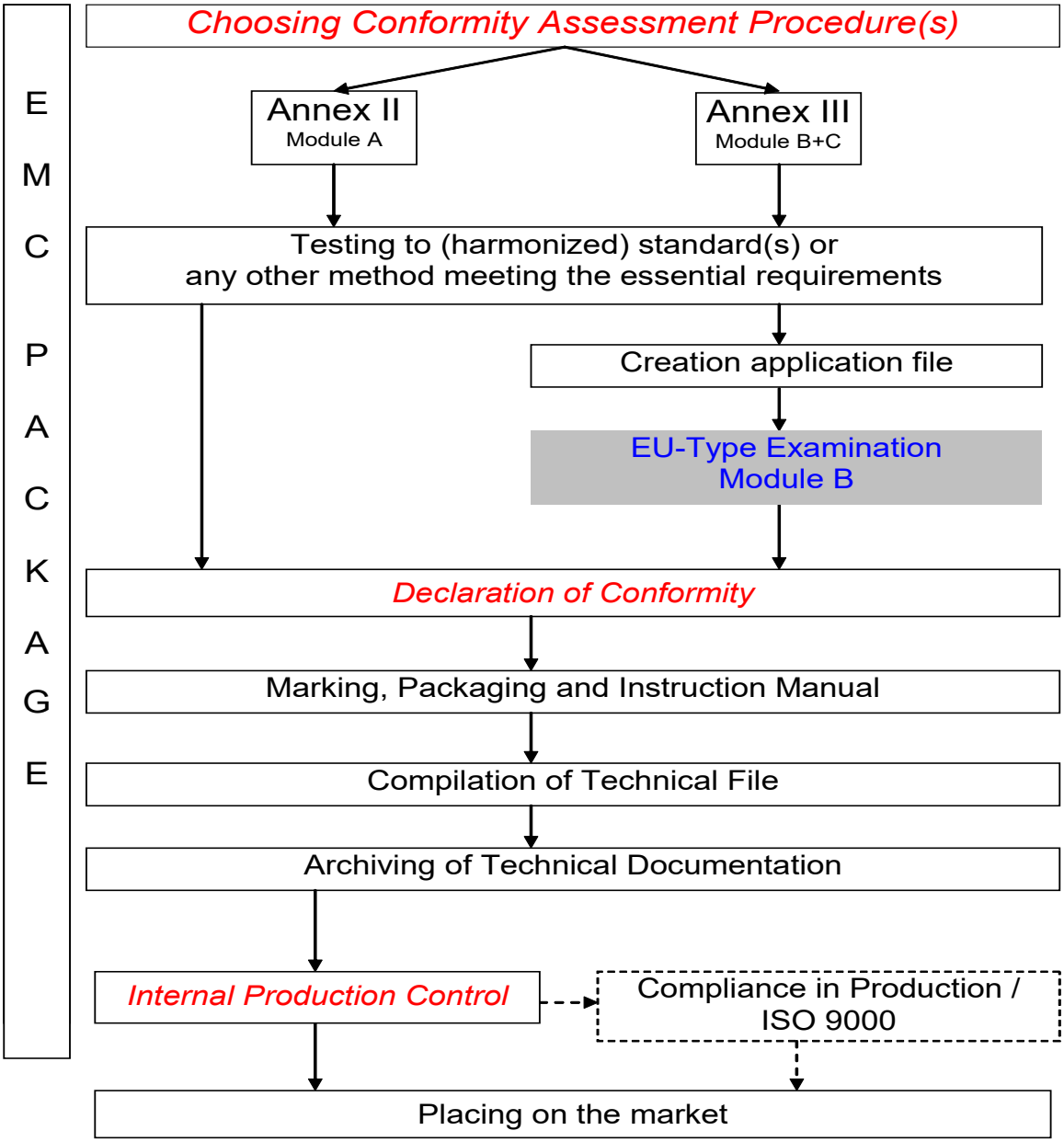

Figure 1: Flow diagram of EMC conformity assessment procedure

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 the gray box with blue letters have to be done by an EMC 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.

2.11.2 Module A: Internal production control

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 annex II of the EMCD. 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 EMCD. 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. So it's a self-declaration procedure and the application of Notified Body service is not mandatory. However Testing services by Kiwa or ISO9000 service might be requested by the manufacturer on a voluntary basis.

2.11.3 Module B+C: EU-type examination + Conformity to Type Based on Internal Production Control

For the conformity assessment procedure B+C the manufacturer assesses both the design and production of his products himself. 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 annex III of the EMCD. 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 EMCD 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 5.3 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.
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 EMCD.
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.

2.11.4 ISO 9000

The ISO 9000 series are aimed primarily at achieving customer satisfaction by preventing non-conformity at all stages from design through servicing. The ISO 9000 series are also of help to ensure all products produced are equal to the product for which compliance to the EMCD was proved. The ISO 9000 series are a general, but suitable tool to fulfil the continued compliance requirement of the EMCD.

2.11.5 Compilation of Technical Documentation

For both conformity assessment procedures Module A and B+C Kiwa can assist in the compilation of the Technical Documentation in accordance EMC Directive, Annex II or III:
The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the essential requirements set out in Article 3. It shall, at least, contain the elements set out in Annex II or III of the EMCD. More details about the technical file in relation to applications to Kiwa are given in Chapter 6 of this document.

2.11.6 Storage of Technical Documentation

For conformity assessment procedures Module B+C, Kiwa will store the technical documentation (and EU declaration of conformity) for at least 10 years after the application for the requested Kiwa service. Also if necessary and requested by the national authority, Kiwa shall provide all the information and documentation necessary to demonstrate the conformity of radio equipment.

2.11.7 Notified Body

For the module B test laboratories have to be used, but also the involvement of a Notified Body is required. Kiwa is an accredited conformity assessment body and notified body who is authorised to implement the tasks relating to the conformity assessment procedure modules B defined by the EMCD. How to apply for these services of Kiwa is described in Chapter 5.

3 Japanese regulations

3.1 The Radio Law

In Chapter III-2 of the Japanese Radio Law the Technical Regulations Conformity Certification of Specified Radio Equipment are defined. This chapter is divided in two sections. In section one the Technical Regulations Conformity Certification and Type Certification of Specified Radio Equipment are defined. In section two is about the Self-Confirmation of Technical Regulations Conformity of Special Specified Radio Equipment.
The products meant in the above section one are within the scope of the CAB Japan certification scheme of Kiwa. See for more information RD_740, Conformity assessment procedure for Radio & Telecommunication Terminal Equipment in Japan.
The products meant in the above section two are within the scope of this certification scheme. It concerns in particularly two groups of products: Radio Receivers and Extremely Low Power Radio Stations.
Radio Receivers have to fulfil the same requirements as the receiver part of Radio Transceivers, which are subject to conformity certification of the above-mentioned section one. In this certification scheme the fulfilment to these requirements is assessed.
Radio Stations are not subject to conformity certification of the above-mentioned section one if the emitted power is below a (frequency dependent) defined value. In that case the Radio Station is called an Extremely Low Power Radio Stations. In this certification scheme the fulfilment to this requirements is assessed.

4 USA regulations

4.1 47 CFR Part 15B (15.101)

(a) Except as otherwise exempted in §§15.23, 15.103, and 15.113, unintentional radiators shall be authorized prior to the initiation of marketing, pursuant to the procedures for certification or Supplier's Declaration of Conformity (SDoC) given in subpart J of part 2 of this chapter, as follows:

Type of device	**Equipment authorization required**
TV broadcast receiver	SDoC or Certification
FM broadcast receiver	SDoC or Certification
CB receiver	SDoC or Certification
Super regenerative receiver	SDoC or Certification
Scanning receiver	Certification
Radar detector	Certification
All other receivers subject to part 15	SDoC or Certification
TV interface device	SDoC or Certification
Cable system terminal device	SDoC or Certification
Stand-alone cable input selector switch	SDoC or Certification
Class B personal computers and peripherals	SDoC or Certification
CPU boards and internal power supplies used with Class B personal computers	SDoC or Certification
Class B personal computers assembled using authorized CPU boards or power supplies	SDoC or Certification
Class B external switching power supplies	SDoC or Certification
Other Class B digital devices and peripherals	SDoC or Certification
Class A digital devices, peripherals and external switching power supplies	SDoC or Certification
Access Broadband over Power Line (Access BPL)	Certification
All other devices	SDoC or Certification

Note to table: Where the above table indicates more than one category of authorization for a device, the party responsible for compliance has the option to select the type of authorization.

(b) Only those receivers that operate (tune) within the frequency range of 30-960 MHz, CB receivers and radar detectors are subject to the authorizations shown in paragraph (a) of this section. Receivers operating above 960 MHz or below 30 MHz, except for radar detectors and CB receivers, are exempt from complying with the technical provisions of this part but are subject to §15.5.

(c) Personal computers shall be authorized in accordance with one of the following methods:

(1) The specific combination of CPU board, power supply and enclosure is tested together and authorized under Supplier's Declaration of Conformity or a grant of certification;

(2) The personal computer is authorized under Supplier's Declaration of Conformity or a grant of certification, and the CPU board or power supply in that computer is replaced with a CPU board or power supply that has been separately authorized under Supplier's Declaration of Conformity or a grant of certification; or

(3) The CPU board and power supply used in the assembly of a personal computer have been separately authorized under Supplier's Declaration of Conformity or a grant of certification; and

(4) Personal computers assembled using either of the methods specified in paragraphs (c)(2) or (c)(3) of this section must, by themselves, also be authorized under Supplier's Declaration of Conformity if they are marketed. However, additional testing is not required for this Supplier's Declaration of Conformity, provided the procedures in §15.102(b) are followed.

(d) Peripheral devices, as defined in §15.3(r), shall be authorized under Supplier's Declaration of Conformity, or a grant of certification, as appropriate, prior to marketing. Regardless of the provisions of paragraphs (a) or (c) of this section, if a CPU board, power supply, or peripheral device will always be marketed with a specific personal computer, it is not necessary to obtain a separate authorization for that product provided the specific combination of personal computer, peripheral device, CPU board and power supply has been authorized under Supplier's Declaration of Conformity or a grant of certification as a personal computer.

(1) No authorization is required for a peripheral device or a subassembly that is sold to an equipment manufacturer for further fabrication; that manufacturer is responsible for obtaining the necessary authorization prior to further marketing to a vendor or to a user.

(2) Power supplies and CPU boards that have not been separately authorized and are designed for use with personal computers may be imported and marketed only to a personal computer equipment manufacturer that has indicated, in writing, to the seller or importer that they will obtain Supplier's Declaration of Conformity or a grant of certification for the personal computer employing these components.

(e) Subassemblies to digital devices are not subject to the technical standards in this part unless they are marketed as part of a system in which case the resulting system must comply with the applicable regulations. Subassemblies include:

(1) Devices that are enclosed solely within the enclosure housing the digital device, except for: Power supplies used in personal computers; devices included under the definition of a peripheral device in §15.3(r); and personal computer CPU boards, as defined in §15.3(bb);

(2) CPU boards, as defined in §15.3(bb), other than those used in personal computers, that are marketed without an enclosure or power supply; and

(3) Switching power supplies that are separately marketed and are solely for use internal to a device other than a personal computer.

5 The application

5.1 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 (only required for EU-type examination)
- Technical documentation

The exact required documentation is indicated in the quick reference guide RX_030.

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, Japan certificate or FCC statement of Review can be issued.

5.2 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 certificate 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

5.3 The certificate

5.3.1 The EU-type examination certificate

For the conformity route concerning Module B+C, as described in section 2.11.3, 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 6 '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 7 'The technical file'.

Annex D shows an example of both trade names.

5.3.2 Japan certificate

Annex D shows an example.

5.3.3 FCC statement of review

Annex D shows an example.

5.4 Follow-up to certificates

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 6 'Modifications following approval'.
Where necessary, Kiwa will issue a follow-up to the certificate.

5.5 General requirements to issue certificates

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

5.5.1 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 2014/30/EU (EMCD).

The manufacturer shall state that the fulfilment of the essential requirements set out in Article 6 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 IV of the EMCD and a copy of that can be found in Annex B of this document.
More Directives can be mentioned on 1 DOC (according NLF).

The content of the DOC (Annex B of this document):

- 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 relevant Union harmonisation legislation
- Description accessories and components.
- Reference to the harmonised standards.
- Where applicable NB number and issued EC type certificate number.
- Signing, date, place of issue.

5.5.2 The Technical File

The manufacturer must compile a technical file. The manufacturer or his authorised representative should keep this file for at least 10 years after the last product has been manufactured. If the manufacturer uses an appointed 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.*

5.5.3 The affixing of markings

EU, Japan and USA legislation require marking of the EMC equipment placed on their markets. Chapter 8 describes the various marking requirements.

5.6 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.

5.7 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 34 of the EMCD the notified body is obliged to report to the notifying authority of any restriction, suspension or withdrawal of certificates.

5.8 Appeal against decisions of notified body

According article 33 Member States shall ensure that an appeal procedure against NB decisions (like restriction, suspension and withdrawal of certificates) is available.

5.9 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.

All issued certificates will be added to the publication list on the Kiwa website: Search radio, wireless and electrical equipment certificates (kiwa.com)

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 previous EMCD 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.

6 Modifications following certification

6.1 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.

6.2 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.

6.3 Change of certificate holder and or manufacturer

The technical construction file assessment 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 technical construction file assessment in question.

Comments

The original holder of the certificate(s) must notify Kiwa in writing that the equipment should be transferred to the name of the new certificate holder.[3] 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 technical construction file assessment certificates 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 technical construction file assessment. The new certificate-holder draws up a Declaration of conformity for each type and sends a copy to Kiwa.

Kiwa will issue an *Addition to the technical construction file assessment certificate*, in which the details of the new certificate holder are stated.

6.4 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.

[3] If the holder has been declared bankrupt, the receiver is the approval-holder.

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.

An Addition to the technical construction file assessment certificate will be issued to the certificate-holder. All the relevant type designations and/or trademarks are listed in an annex.

6.5 Addition of new product 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 technical construction file assessment certificate, 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.

The manufacturer or importer draws up a new *Declaration of conformity* and sends a copy to Kiwa. Kiwa issues an Addition to the technical construction file assessment certificate, in which the relevant type designations and/or trademarks are listed.

6.6 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 additional test report(s) and all other altered documentation are submitted to Kiwa together with a modification application.

The manufacturer or importer draws up a new *Declaration of conformity* and sends a copy to Kiwa. Kiwa issues an Addition to the technical construction file assessment certificate.

6.7 Modifications due to changing requirements

As described in section 2.11.3 and 5.9 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.

6.8 Modifications not affecting the requirements

Modifications of equipment that do not and cannot affect conformity with the requirements and do not involve changes to the details of the manufacturer, applicant and product description, do not need to be notified to Kiwa. However, if the modifications do effect the physical outlining of the product, adequate information for identification purposes needs to be provided to Kiwa.

If you are in any doubt, contact Kiwa.

7 The technical file

7.1 Introduction

The regulations require the manufacturer to compile a technical file. This file should contain all the data that can be used to show that the product conforms to the requirements of these Directives.

This section provides further information on the scope, content and form of the technical file.

7.2 Purpose of the technical file

The applicable legal requirements require the manufacturer to compile a technical file. This file should contain all the data, which can be used to show that the product conforms to these requirements.

This section provides further information on the scope, content and form of the technical file.

The technical file plays a key role in the conformity assessment of a product. The manufacturer assesses the product himself 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 or importer to provide data showing that a product satisfies the requirements. If the manufacturer or importer is unable or unwilling to supply this data, this provides sufficient grounds for questioning the *'presumption of conformity'* with the laws in question or for imposing sanctions.

The technical file is one of the elements for carrying out a technical construction file assessment with the involvement of a third party (i.e. a Notified Body). In such cases, the certificate relating to this technical construction file assessment also forms part of the technical file.

7.3 Form and content of the technical file

The conformity assessment procedures are mainly intended to enable government bodies to make sure that the products placed on the market satisfy the statutory requirements. The manufacturer should be able to demonstrate by means of the technical file that the requirements are met.

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 the requirements. 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:

- a first part containing a list of essential technical data necessary for the conformity assessment inspection, such as:
  - name and address of the manufacturer, and the type designation of the product;
  - the list of the harmonised standards applied by the manufacturer and/or the solutions he has adopted to satisfy the essential requirements;
  - a description of the product;
  - the manual, where applicable;
  - a general drawing of the product, where applicable;
  - records of complaints regarding the certified product(s).
- a second part, consisting of a complete file containing all the test reports, information on the quality manual, plans, descriptions of the products and processes, applied standards, etc.

7.4 Availability of the technical file

The technical file should always be kept available to the national authorities for inspection purposes and to Kiwa. In Europe it is 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 or his authorised representative and importer established in the Community.

According to European law the file should be kept for at least ten years after the date on which the product was last manufactured.

8 Markings

8.1 The different markings in Europe, Japan and USA

All products that are within the scope of the EMC Directive are subject to CE marking. The exact form and conditions are described in paragraph *8.2 The European CE Marking*.

Radio transmitting products, which do not fall under the scope of the Japanese Radio Law, are not subject to any legal marking.

All products that are within the scope of 47 CFR Part 15B are subject to FCC marking. The exact form and conditions are described in paragraph *8.3 The USA FCC Marking*.

8.2 The European 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 EMCD 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:

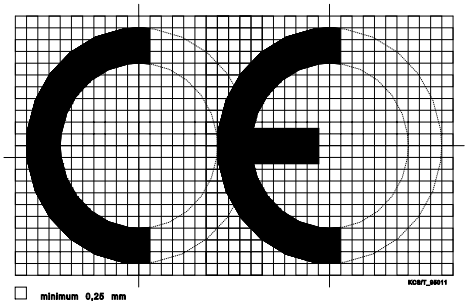

Figure 2: The initials CE.

- 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 equipment 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

8.3 The USA FCC marking

General marking for SDoC

The product identification (labeling) and compliance information requirements for a device subject to SDoC (Sections 2.1074 and 2.1077, respectively) requires that each device be uniquely identified (for example, using a label listing a trade name and type or model number), and that end-users must be provided with a compliance information statement for the product.
The unique identifier is any means to positively associate the device with the compliance test reports and records for a specific product approved using the SDoC procedure.6 This may be a trade name and type number, model number, serial number, or other means employed utilizing the responsible party's internal manufacturing process.

Compliance Information
A compliance information statement that includes the following items (Section 2.1077(a)) must be supplied with the product at the time of marketing or importation:
Identification of the product, e.g., trade name, model, etc.

- A statement that the product complies with the rules, as applicable (e.g. Part 15 or 18); and
- The name and address, and telephone number, or internet contact information of the responsible party's (as defined in Section 2.909(b)) contact located in the United States.

Marking RF devices

In Chapter 47 CFR, Part 15, Section 15.19 the labelling requirements are given:

(a) In addition to the requirements in part 2, a device subject to certification, or Supplier's Declaration of Conformity shall be labeled as follows:
(1) Receivers associated with the operation of a licensed radio service, e.g., FM broadcast under part 73 of this chapter, land mobile operation under part 90 of this chapter, etc., shall bear the following statement in a conspicuous location on the device:
This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.
(2) A stand-alone cable input selector switch, shall bear the following statement in a conspicuous location on the device:
This device complies with part 15 of the FCC Rules for use with cable television service.
(3) All other devices shall bear the following statement in a conspicuous location on the device:
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
(4) Where a device is constructed in two or more sections connected by wires and marketed together, the statement specified under paragraph (a) of this section is required to be affixed only to the main control unit.
(5) When the device is so small or for such use that it is impracticable to label it with the statement specified under paragraph (a) of this section in a font that is four-point or larger, and the device does not have a display that can show electronic labeling, then the information required by this paragraph shall be placed in the user manual and must also either be placed on the device packaging or on a removable label attached to the device.
(b)-(c) [Reserved]

(d) Consumer electronics TV receiving devices, including TV receivers, videocassette recorders, and similar devices, that incorporate features intended to be used with cable television service, but do not fully comply with the technical standards for cable ready equipment set forth in §15.118, shall not be marketed with terminology that describes the device as "cable ready" or "cable compatible," or that otherwise conveys the impression that the device is fully compatible with cable service. Factual statements about the various features of a device that are intended for use with cable service or the quality of such features are acceptable so long as such statements do not imply that the device is fully compatible with cable service. Statements relating to product features are generally acceptable where they are limited to one or more specific features of a device, rather than the device as a whole. This requirement applies to consumer TV receivers, videocassette recorders and similar devices manufactured or imported for sale in this country on or after October 31, 1994.

8.3.1 FCC logo

Devices authorized under the SDoC procedure have the option to use the FCC logo to indicate compliance with the FCC rules,12 and the logo may be included in the instruction materials or as part of an e-label

Figure 3: FCC logo

The FCC logo shall only be used on a product that has been tested, evaluated, and found to be compliant in accordance with the SDoC procedures. The use of the FCC logo on the device does not mitigate the requirement to provide a means to uniquely identify the product or to provide the required compliance information statement. The FCC logo cannot be used on products that are exempt from an authorization by rule (e.g., Section 15.103 exempt devices, or Section 15.3 incidental radiators) unless the SDoC procedure has been fully applied for the product.

8.3.2 Electronic labelling

Products with a built-in display, or that only operate in conjunction with another product that has an electronic display, have the option to display on the electronic display the FCC Identifier, any warning statements, or other information that the Commission's rules would otherwise require to be shown on a physical label attached to the device. See 47 CFR § 2.935. Guidance for electronic labeling is provided in a separate attachment–see KDB Publication 784748 D02.

Annex A Abbreviations and paraphrases

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 in the Directive.

CE marking
A mark consisting of one or more symbols, indicating that the product in question conforms to all the applicable Directives.

Certificate-holder
The person to whom a technical construction file assessment Certificate is granted.

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).

Compulsory certification
Certification required by a regulation or Directive before a product, process or service may be placed on the market.

Compulsory conformity assessment
Conformity assessment relating to requirements laid down in regulations or Directives which must be undertaken before a product, process or service may be placed on the market.

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

Declaration of conformity
The Declaration of conformity is a document drawn up by the manufacturer, supplier or importer himself. It should indicate that the product concerned conforms to the standard(s) and Directive(s) to which the declaration refers. A model of the Declaration of conformity is described in standard EN45014, *General criteria for suppliers' declaration of conformity*.

When a EC type-examination is part of the conformity assessment process, a Declaration of conformity must be drawn up. In this declaration one may refer to all applicable standards.

Technical construction file assessment procedure
A certification procedure whereby a Notified Body assesses the technical construction file of the equipment/product.

EEA
The European Economic Area (EEA)

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

Essential requirements
These are general criteria which products must satisfy before they may be placed on the market of the EEA.

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.

Agentschap Telecom
The Radio Communications Agency of the Ministry of Economic Affairs.

Importer
Any person within EU who places on the market of the EEA, a product from a third country.

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

Kiwa
Notified Body under the EMC Directive 2014/30/EU.

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

Notified Body
A Notified Body is a third party authorised to carry out the tasks relating to approvals described in a European Directive. A Notified Body is designated by the Member 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 the “Notified body”.

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

Placing on the market
The first moment when a product, covered by a Directive, being made available, for payment or free or charge, on the market of the EEA with a view to its distribution and/or use in the territory of the EEA.

Putting into service
The first use by the end user within the EEA, of a product covered by a Directive.

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.

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.

Trademark
Trademark refers to the generic (brand) name under which certain a radio transmitter is marketed.

Type designation
Type designation refers to the unique name under which certain a radio transmitter is marketed.

Annex B The Declaration of Conformity

The Declaration of Conformity (DoC) is a document drawn up by the manufacturer, supplier or importer himself. The purpose of the declaration is to indicate that the product in question conforms to the standard(s) and Directive(s) to which the declaration refers. A model of the Declaration of Conformity is described in the standard EN45014, *General criteria for suppliers' declaration of conformity*.

Europe
All new-approach Directives require a Declaration of Conformity (to type) to be drawn up for each product. If multiple Directives apply you may also draw up one declaration for all these Directives together, in which you specify all the standards and references of all applicable Directives.

Japan
No Declaration of Conformity is required according to the Japanese Radio Law.

USA
The Declaration of Conformity procedure of the FCC requires a Declaration of Conformity to be drawn up for each product.

B.1 Content of the declaration

The declaration must contain sufficient information to identify all the products referred to. At least the following information must be provided:

- the name and address of the manufacturer/importer issuing the declaration;
- the identification of the product (name, type or model, batch or serial number, possibly the origin and numbers of articles);
- an accurate, complete and clear statement of the standards and/or technical solutions referred to;
- the date of issue;
- name and signature or equivalent authentication of the authorised representative;
- the statement that the declaration has been issued entirely on the responsibility of the manufacturer/importer;
- a reference to the Directives or Law(s) that apply.

B.2 Drawing up a declaration

It is recommended that declarations are drawn up on letter headed paper of the company and that original copies are forwarded to Kiwa together with the application in question. However, Kiwa can provide you with some generic declaration forms to complete. See the two models below.

Model 1: The Declaration of conformity to type relating to Directive 2014/30/EU

EU declaration of conformity (No Xxxx)

1. Apparatus model/Product (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 apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

7. Where applicable, the notified body … (name, number) performed … (description of intervention) and issued the certificate:

8. Additional information:
Signed for and on behalf of:
(place and date of issue):
(name, function) (signature):

Model 2: The Declaration of conformity to type relating to 47 CFR Part 15B

FCC

FEDERAL COMMUNICATIONS COMMISSION DECLARATION OF CONFORMITY (SDoC)

Equipment:
Trademark(s) and Model(s):
Manufacturer:

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

The following documents are subject for this declaration:

Test Report(s):

The following local manufacturer/importer/entity is responsible for this declaration:

Company name:……

Name/Title (legal representative):……

Address:……

……

Phone:……

Fax:……

E-mail (if available):……

Date:……Signature:……

Annex C 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 EMC.

For technical construction file assessments:

RD_030	Conformity assessment procedures regarding Electromagnetic compatibility (this document)
RD_103	The CE Marking
RD_108	FCC Part 15B Marking
RF_100	General Application form
RF_061	Declaration of Conformity (EMC Directive 2014/30EU)
RF_260	Declaration of Conformity (Part 15B)
RQ_160	Termination (expiration), reduction, suspension and withdrawal of Certificates

Kiwa can provide you with original copies of these forms, but you may also use photocopies or printouts obtained from our web site.

Annex D Examples of Certificates and Statements

D.1 European EU-Type examination

Example of an **EU-Type examination** showing conformity to 2014/30/EU.

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 no Annexes.		

In compliance with the procedure specified in the **EMC Scheme** RD_030, Kiwa Nederland B.V. declares as designated Notified Body 0063 for the Electromagnetic Compatibility (EMC) Directive, that the stated product complies with the essential requirements, in accordance with Article 6 of Directive 2014/30/EU, based on the applicable technical standards and specifications as listed on this certificate. The validity of this certificate is limited to products which are equal to the one examined.

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

This certificate is granted to:

Name: certificate holder:
Address:
City:
Country:

Technical documentation:
Report or File No.: <report>
Report or File date: <date report>

Applied Standards and covered Phenomena:
<list standards> <date standard>

This certificate remains valid as long as the stated product stays in compliance with the essential requirements of the EMC directive.

PRODUCTS
RvA C 002

Ron Scheepers
Managing director

Kiwa Nederland B.V.
Wonsteed 50
Postbus 137
7300 AC Apeldoorn
The Netherlands

https://www.kiwa.com/nl/en/market/radio-wireless-and-electrical-equipment/

Chamber of commerce
08090048

D.2 Japan Certificate

CERTIFICATE

Certificate of
Extremely low power Radio Equipment in JAPAN
<certificate number>

Issued	<date>	Date of expiration of validity <certificate number>
Page	<Page> of <NumPages> This certificate has no Annexes.	First issued <date>

Kiwa Nederland B.V., operating as Japan Conformity Assessment Body (CAB ID Number: 201), declares that with respect to the provisions of the Japanese Radio Regulations, for the listed Extremely Low power Radio Stations and Receiving Equipment, certification is not mandatory. Kiwa has reviewed the relevant product properties in the following documentation:

Test Reports: <list reports>

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

Manufacturer: <xxx>
Address: <xxx>
City: <xxx>
Country: <xxx>

This certificate is granted to:

Name: certificate holder:
Address:
City:
Country:

Kiwa Nederland B.V.
Wilmsdad 50
Postbus 137
7300 AC Apeldoorn
The Netherlands

https://www.kiwa.com/nl/en/market/wireless-and-electrical-equipment/

Chamber of commerce
08090048

Ron Scheepers
Managing director

PRODUCTS
RvA C 002

Annex E Additional information

For more information contact:

Kiwa Nederland B.V.

Phone: +31 88 998 3600
Fax: +31 316583189
Email: ECP@Kiwa.com

Mailing Address:
Wilmersdorf 50
7327 AC Apeldoorn
The Netherlands

Web-site: http://www.Kiwa.com