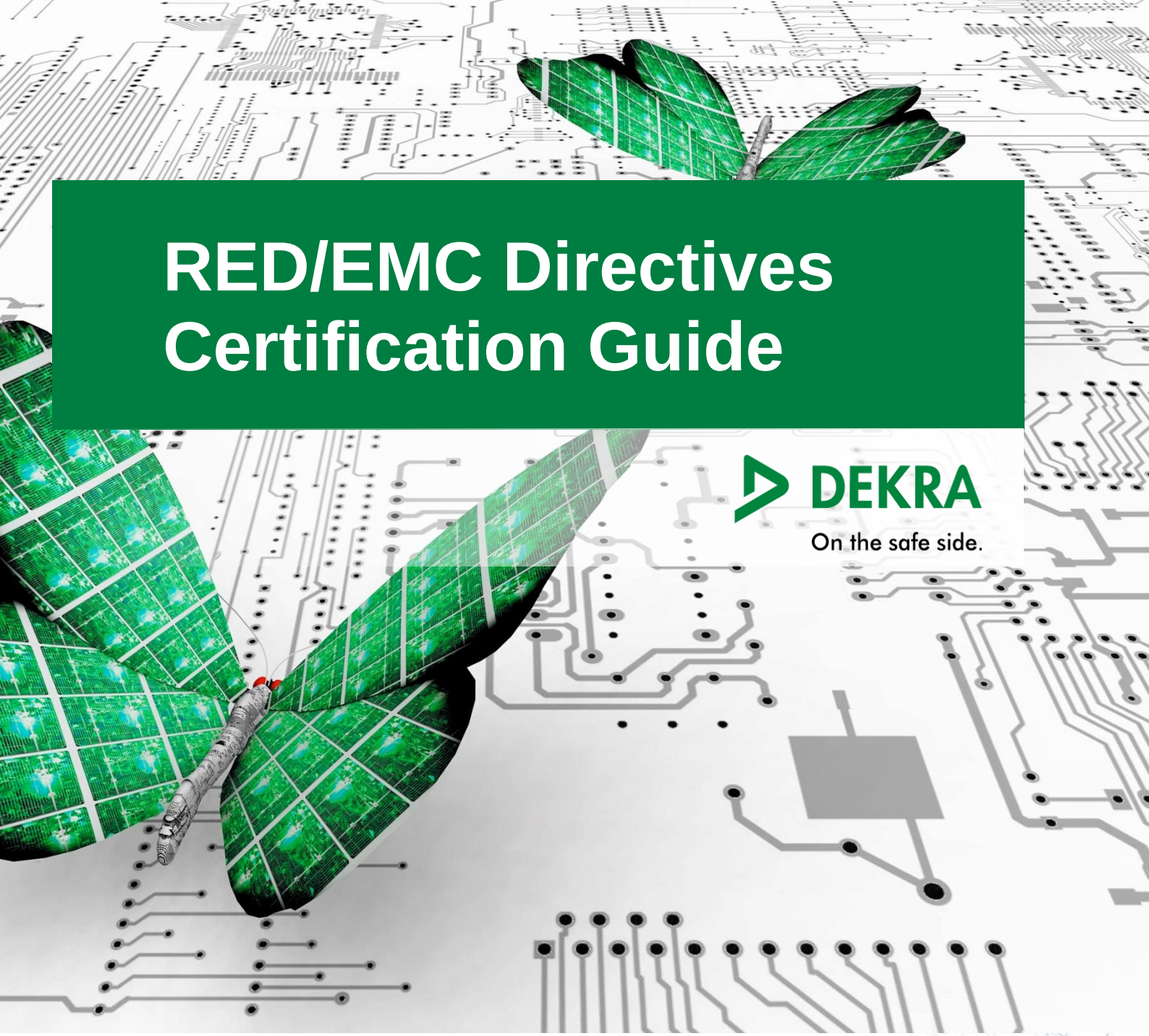
RED/EMC Directives Certification Guide



DEKRA

On the safe side.

This document is a guide to apply for Radio Equipment Directive (2014/53/EU) EU Type Examination Certification and EMC Directive (2014/30/EU) EU Type Examination Certification through DEKRA as NB for RED and EMC Directive.

This document is provided for information purpose only and always the official EU regulations prevail.

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1. Introduction

DEKRA has been notified as Notified Body for certification according to the Radio Equipment Directive (2014/53/UE) and EMC Directive (2014/30/UE) by the Secretaría de Estado para la Sociedad de la Información y la Agenda Digital and Subdirección General de Calidad y Seguridad Industrial / Ministerio de Energía, Turismo y Agenda Digital.

DEKRA, as NB, only applies the existing EU rules and cannot interpret them. DEKRA review will be based on the provided documentation and information, but the applicant remains responsible for the compliance of the device with all the applicable regulations.

This guide covers the DEKRA review and final decision about certification activities following the Conformity Assessment specified in **Annex III** of RE and EMC directives. Testing activities are not covered by this guide.

1.1. RED certification scope

Products:	All radio equipment except equipment listed in Annex I of Directive 2014/53/EU (RED) or 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 are defined as: an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radiodetermination.
Conformity assessment procedures:	Annex III – Module B

1.2. EMC Directive certification scope

Products:	All equipment except those indicated in Art. 2.2 of Directive 2014/30/EU (EMC). Equipment are defined as: - 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; or - 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;
Conformity assessment procedures:	Annex III – Module B

2. Application for equipment certification

2.1. How can you apply?

You can request a quote for certification according to RED or EMC Directive by one of the following means:

- Sending an e-mail to your Account Manager at DEKRA or to the e-mail address: infolab.es@dekra.com.
- Sending a fax to the number: +34 952 619 113

Please specify in your request the detailed technical specifications of the device, the scope of the certification request (RED or EMC Directive) and any additional service you may need before the certification activities (e.g. testing).

Once received your request, DEKRA will assign an Account Manager that will contact you to clarify any possible doubt about your request and to provide the service quote.

After accepting the service quote for certification activities, you may submit the documentation and information required for certification to the e-mail address: certification.rcb.es@dekra.com. In case that all the documentation cannot be attached to a single e-mail you may either send several e-mails or to set up an FTP account where the certification body may access to download the required information.

The responsible for the certification body will then assign a reviewing engineer who will be your main point of contact during the review process.

The manufacturer shall lodge an application for EU-type examination only with a single notified body of his choice.

2.2. Signatory/Agent

All the applications forms, declarations, cover letters, etc. submitted for certification must be signed by the manufacturer or its authorized representative.

Note that regardless of who submits the project to the Notified Body; the EU Type Examination Certificate would be always issued in the name of the manufacturer who places the product onto the market, with their brand name and company details on the product.

3. Type of applications

3.1. Original Certification

Application for a new device. Test report showing compliance with all the requirements of the applicable technical requirements is required to be submitted as support to the application.

3.1.1. Integration

For RED, in the case where a radio module is integrated, the person integrating the module becomes the manufacturer of the final product and is therefore responsible for demonstrating compliance of the final product with the essential requirements of the RE Directive.

Assessment of the final product (which integrates the RED assessed module) must be made against the Essential requirements of the RED Articles 3.1(a), 3.1(b) and 3.2. It should be noted that assessment does not necessarily lead to testing. Assessment may include technical analysis, design evaluation and testing.

3.2. Modification of an existing EU-type examination certificate

A modification of the certification includes those modifications which modify the performance characteristics as reported at the time of the initial certification. Such modified performance must still meet the minimum requirements of the applicable standards. When a request for Modification of Certification is made by the manufacturer, the manufacturer shall supply complete information and the results of tests of the characteristics affected by such change. The modified equipment shall not be marketed under the existing EU Type Examination Certificate prior to the issue of the new Certificate covering the modification.

3.3. Family/System Certification and adding product variants to an existing EU-type examination certificate

Family/system certification is not defined in Directive 2014/53/EU, so than only the criteria of the Notified Body would need to be considered to include several devices in a single EU-TEC.

Family/system certification (multiple models) may be granted to many models of equipment that are similar equipment in function, appearance and design; or belong to a system of devices which interact together.

It shall be considered if models are similar on a case-by-case basis. The important premise is that every model is evaluated and evidences of compliance with essential requirements are provided.

4. Required documentation

The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that equipment complies with the essential requirements set out in Article 3 of Radio Equipment directive for devices covered by the RED or Annex II of EMC directive for devices covered by such directive.

The technical documentation shall be drawn up before equipment is placed on the market and shall be continuously updated.

The technical documentation and correspondence relating to any EU-type examination procedure shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

The following content is required (as appropriate to your particular application):

4.1. RED type of applications

The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of the Directive and shall include an adequate analysis and assessment of the risk(s).

Document	Description	Mandatory for		
		Original	Modification / Adding variant	Integration
RED form	Application form for RED certification services	X	X	X
Risk Assessment	A risk assessment analyzing the possible risks and demonstrating how they are reduced to comply with the essential requirements.	X	X (1)	X
Technical specifications	General features, RF specifications (frequency bands, modulations, duty cycle, output power, etc.), power supply specifications …	X	X	X
Antenna specifications	Specifications, datasheet, gain, etc. of the antenna used with the device.	X	X (1)	X
Block diagram	A block diagram showing the frequency of all the oscillators in the device. The signal path, frequency and intermediate frequencies shall be indicated at each block.	X	X (1)	X
Technical description	A description of the circuit functions of the device along with a description about how the device operates. This statement should contain a description of the ground system and antenna, if any, used in the device.	X	X	X
Schematics	Electrical diagrams	X	X (1)	X
Mechanical diagrams	PCB layout and component placement diagrams	X	X (1)	X
Bill of materials	List of components	X	X(1)	X
User's guide	A copy of the installation and operating instructions to be furnished the user including all regulatory notices	X	X(1)	X
Tune up info	For 2G/3G/4G devices	X	X(1)	X
Internal photographs	Internal photographs of the device showing all the boards and PCB in the equipment. At least one of the photographs has to show the RF module with the RF shielding removed.	X	X(1)	X
External photographs	External photographs of the device showing the overall appearance, the antenna used with the device, the controls available to the user and the required identification label.	X	X(1)	X
Electrical safety test report	Test report showing compliance with electrical safety essential requirement (Art. 3.1(a))	X	X(1)	X
EMF exposure test report/calculation	SAR report/MPE calculation showing compliance with health (EMF (electromagnetic fields) exposure) essential requirement (Art. 3.1(a))	X	X(1)	X
EMC test report	EMC test report showing compliance with EMC essential requirement (Art. 3.1(b))	X	X(1)	X
RF test report	RF test report showing compliance with efficient radio spectrum use essential requirements (Art. 3.2)	X	X(1)	X
Specific test report	Test report showing compliance with essential requirements against articles 3.3 (Ex: cybersecurity test report for articles 3.3 (d) (e) (f))	X	X(1)	X

RED Annex V declaration	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).	X	X(1)	X
EU DoC	Draft or final version of the EU DoC are both acceptable	X(6)	X(6)	X(6)
Authorisation letter	If an agent submits the application, an authorisation letter from the applicant/manufacturer to the agent must be provided.	X	X	X
HW/SW changes declaration	Detailed description of the differences between the tested device and the version that would like to be certified.	X(2)	X(2)	X(2)
Rationale of compliance	Technical justification why the test results remain applicable, valid and representative for the version to be certified.	X(3)	X(3)	X(3)(4)
Block diagram of the module	A block diagram showing the frequency of all the oscillators in the device. The signal path and frequency shall be indicated at each block. The intermediate frequency shall be indicated at each block.			X(5)
Technical description of the module	A description of the circuit functions of the device along with a description about how the device operates. This statement should contain a description of the ground system and antenna, if any, used in the device.			X(5)
Schematics of the module	Electrical diagrams			X(5)
Mechanical diagrams of the module	PCB layout and component placement diagrams			X(5)
Bill of materials of the module	List of components			X(5)
Test report of the module	RF and/or EMF exposure test reports/calculations from the module which the client claims to be applicable, valid and representative for the product to be certified.			X(5)

(1) Required if different from the originally submitted.
(2) Required if the version tested is different from the version to be approved.
(3) Detailed description of the differences between the modified device and the previously certified device, with particular emphasis on the following aspects:

- the radio frequency and RF output power;
- the radio frequency circuitry;
- functional capabilities;

Detailed description of the software changes, with particular emphasis on the following aspects:

- the radio frequency and RF output power;
- the radio frequency circuitry;
- functional capabilities;

It should include a brief statement as to why the modified product still complies with EU regulation.
(4) In the case where integration of a module requires assessment involving the submission of a TCF to a Notified Body and the module manufacturer has not made his technical documentation (*) available to the final product manufacturer, the module manufacturer will be asked to make the module documentation available directly to the Notified Body. Not having the module documentation may prevent the Notified Body from delivering an opinion on the TCF to the final product manufacturer. Accordingly, the final product manufacturer must ensure that their module manufacturer is aware of this need and is willing to provide the relevant documentation direct to the Notified Body. It is not required that the final product manufacturer's TCF include the module manufacturer's proprietary documentation. However, note that if a market surveillance authority wishes to inspect the TCF, they will most likely request to see the module technical information.
(5) In case the EU-TEC of the module is provided, the evaluation of this document is not required.
(6) The DoC must be part of the Technical Documentation but it is not mandatory to submit it to the Notified Body. The content of such document will not be reviewed to evaluate the compliance of the equipment with the essential requirements.

4.2. EMC Directive type of applications

Document	Description	Mandatory for	
		Original	Modification / Adding variant
Application form	Document including equipment, applicant, manufacturer, TCF and standards information	X	X
Technical specifications	General features, RF specifications (frequency bands, modulations, duty cycle, output power, etc.), power supply specifications …	X	X
Block diagram	A block diagram showing the frequency of all the oscillators in the device. The signal path, frequency and intermediate frequencies shall be indicated at each block.	X	X(1)
Technical description	A description of the circuit functions of the device along with a description about how the device operates. This statement should contain a description of the ground system and antenna, if any, used in the device.	X	X
Schematics	Electrical diagrams	X	X(1)
Mechanical diagrams	PCB layout and component placement diagrams	X	X(1)
Bill of materials	List of components	X	X(1)
User's guide	A copy of the installation and operating instructions to be furnished the user including all regulatory notices	X	X
Internal photographs	Internal photographs of the device showing all the boards and PCB in the equipment. At least one of the photographs has to show the RF module with the RF shielding removed.	X	X(1)
External photographs	External photographs of the device showing the overall appearance, the antenna used with the device, the controls available to the user and the required identification label.	X	X(1)
Label design	Including: brand name, model name, CE marking, etc.	X	X(1)
EMC test report	EMC test report showing compliance with EMC essential requirement (Art. 3.1(b))	X	X(1)
Authorisation letter	If an agent submits the application, an authorisation letter from the applicant/manufacturer to the agent must be provided.	X	X(1)
HW/SW changes declaration	Detailed description of the differences between the tested device and the version that would like to be certified.	X(2)	X(2)
Rationale of compliance	Technical justification why the test results remain applicable, valid and representative for the version to be certified.	X(3)	X(3)
Risk Assessment	A risk assessment analyzing the possible risks and demonstrating how they are reduced to comply with the essential requirements.	X	X (1)

(1) Required if different from the originally submitted.
(2) Required if the version tested is different from the version to be approved.
(3) Detailed description of the differences between the modified device and the previously certified device, with particular emphasis on the following:

- digital devices circuitry;
- crystals, clocks and PCB changes;
- power supply circuitry and components;
- accessible ports;
- functional capabilities;

Detailed description of the software changes, with particular emphasis on the following:

- firmware of digital devices included in the product (e.g. microprocessors, I/O signal processors,..);
- functional capabilities;

It should include a brief statement as to why the modified product still complies with EU regulation.

5. Disclosure of Information

The documentation provided will be stored in specific location in the DEKRA internal network which will be only accessible by the certification body staff except as follows:

- During the accreditation/notification procedure information and documentation of some specific certification projects may be available to the accreditation body or notifying authority.
- When required by law to release confidential information the applicant will be notified except if this notification is forbidden by law.

The confidential information obtained or created during the performance of certification activities may also to be accessed by the members of the Impartiality Committee, external to the CB, and by the accreditation body.

Notified bodies shall inform of any issue, refusal, restriction, suspension or withdrawal of EU Type Examination certificates following the provisions stated in:

- Radio Equipment Directive: Article 34 and Annex III – Part A – Module B – Item 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 harmonised 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

- EMC Directive: Article 36 and Annex III – Part A – Module B – Item 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.

6. Labelling information

6.1. RED labelling requirements

The equipment should be labelled with the following information:

- Type designation, batch and/or serial number or other element allowing its identification
- Manufacturer data (name, registered trade name or registered trade mark and the postal address at which he can be contacted).
- Importer data (name, registered trade name or registered trade mark and the postal address at which he can be contacted).
- CE marking:
  - The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.
  - The CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of radio equipment.

6.2. EMC Directive labelling requirements

The equipment should be labelled with the following information:

- Type designation, batch and/or serial number or other element allowing its identification
- Manufacturer data (name, registered trade name or registered trade mark and the postal address at which he can be contacted).
- Importer data (name, registered trade name or registered trade mark and the postal address at which he can be contacted).

- CE marking:
    - The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
    - The CE marking shall be affixed visibly, legibly and indelibly to the apparatus or to its data plate. Where that is not possible or not warranted on account of the nature of the apparatus, it shall be affixed to the packaging and to the accompanying documents.

Where the size or nature of the apparatus does not allow placing the type designation, batch and/or serial number or other element allowing its identification on the apparatus, the required information is provided on the packaging or in a document accompanying the apparatus

The contact details of manufacturers and importers shall be in a language easily understood by end-users and market surveillance authorities. Where it is not possible to place this information on the apparatus, it must be shown on its packaging or in a document accompanying the apparatus.

7. Required notices to the user

7.1. RED user's manual requirements

The radio equipment must be accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended.

Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The following information shall also be included in the case of radio equipment intentionally emitting radio waves:

- frequency band(s) in which the radio equipment operates;
- maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

Each item of radio equipment must be accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. Where a simplified EU declaration of conformity is provided, it shall contain the exact internet address where the full text of the EU declaration of conformity can be obtained.

Simplified EU DoC:

> Hereby, **[Name of manufacturer]** declares that the radio equipment type **[designation of type of radio equipment]** is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:

In cases of restrictions on putting into service or of requirements for authorization of use, information available on the packaging shall allow the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorization of use exist. Such information shall be completed in the instructions accompanying the radio equipment. The Commission may adopt implementing acts specifying how to present that information. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 45(2).

In case the size or nature of the radio equipment does not allow it to bear a type, batch or serial number or other element allowing its identification, the required information must be provided on the packaging, or in a document accompanying the radio equipment.

In case the manufacturer data (name, registered trade name or registered trade mark and the postal address at which he can be contacted) cannot be included in the radio equipment, this information must be on its packaging, or in a document accompanying the radio equipment.

In case the importer data (name, registered trade name or registered trade mark and the postal address at which he can be contacted) cannot be included in the radio equipment, this information must be on its packaging, or in a document accompanying the radio equipment.

7.2. EMC Directive user's manual requirements

Apparatus shall be accompanied by instructions and the information referred to in Article 18 of the directive in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

Apparatus shall be accompanied by information on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the essential requirements set out in point 1 of Annex I of the directive.

Apparatus for which compliance with the essential requirements set out in point 1 of Annex I is not ensured in residential areas shall be accompanied by a clear indication of such restriction of use, where appropriate also on the packaging.

The information required to enable apparatus to be used in accordance with the intended purpose of the apparatus shall be included in the instructions accompanying the apparatus.

8. Certification process overview

8.1. Administrative Review

When all the required information has been received by DEKRA, DEKRA's administrative review will examine the documents to determine if all submittal information is complete, accurate, and correctly prepared for certification. A complete application is required before the technical review can begin and before the application can be processed. Once the reviewer has determined that all necessary documents are present, the application documents will be forwarded to the technical reviewer.

If information/documentation is missing during the administrative review, the applicant will be informed about the administrative or technical information that is still needed. The applicant will also be informed they have 30 days to respond before the application is dismissed.

If the application is dismissed, DEKRA shall arrange for all test data, exhibits, samples, or other related items to be deleted or returned to the applicant. DEKRA will also notify the client of a decision not to grant certification, and will identify the reasons for the decision.

8.2. Technical Review

Next, a technical review shall be performed by DEKRA to determine if the applicant's test data and report satisfy the applicable requirements.

A Technical Review of the application shall be performed. Items relating to the conformance of the equipment to the necessary technical requirements shall be evaluated, including, but not limited to:

- Test procedures performed
- Test data
- Test equipment used including information about its calibration status
- User's Manual
- Schematics and block diagram supplied by the manufacturer
- Operational Description Supporting descriptions, if necessary
- Plots or other data, if necessary

If information/documentation is missing during the technical review, the applicant will be informed about the information is still needed. The applicant will also be informed they have 30 days to respond before the application is dismissed.

If the application is dismissed, DEKRA shall arrange for all test data, exhibits, samples, or other related items to be deleted or returned to the applicant. DEKRA will also notify the client of a decision not to grant certification, and will identify the reasons for the decision.

8.3. Decision about certification

After DEKRA has completed the administrative review and the technical review, the findings from each shall be forwarded to the responsible for certification. The responsible for certification shall analyze the findings and the recommendations from the administrative and technical revisions and then present a decision to the applicant and will review that the documentation provided is complete to take a decision about the certification of the device.

If the responsible for certification determines that the device fails to meet the requirements, DEKRA shall immediately notify the applicant in writing regarding the specific cause of the negative finding. The applicant will also be informed they have 30 days to respond before the application is dismissed.

If the application is dismissed, DEKRA shall arrange for all test data, exhibits, samples, or other related items to be deleted or returned to the applicant. DEKRA will also notify the client of a decision not to grant certification, and will identify the reasons for the decision.

8.4. Filing Applications and equipment authorization certificate

Upon successful approval by responsible for certification, DEKRA directly generates an EU Type Examination Certificate. Notified bodies shall inform of any issue, refusal, restriction, suspension or withdrawal of EU Type Examination certificates following the provisions stated in:

Radio Equipment Directive: Article 34 and Annex III – Part A – Module B – Item 8

EMC Directive: Article 36 and Annex III – Part A – Module B – Item 8

8.5. Retention of records

DEKRA will retain, for 10 years, all documentation furnished in support of an application for certification and may make such documentation available to the competent national authorities of the Member States upon request received from them.

9. Product modifications

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 apparatus 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.

For changes that do not change the performance characteristics of the certified device, the applicant is not required to submit an application to DEKRA, but the applicant is required to keep a record of the modifications to the device.

10. Product Audit Requirements

It is responsibility for competent market surveillance authorities to perform the surveillance of the compliance of the devices with the provisions of the RE and EMC Directives.

However 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 these directives and shall determine whether such changes require further investigation. If so, DEKRA will inform the manufacturer accordingly. In addition, DEKRA may request information, such us product modifications or internal production controls, to the manufacturer about the approved type in order to determine if the validity any issued EU Type Examination Certificate may be affected.