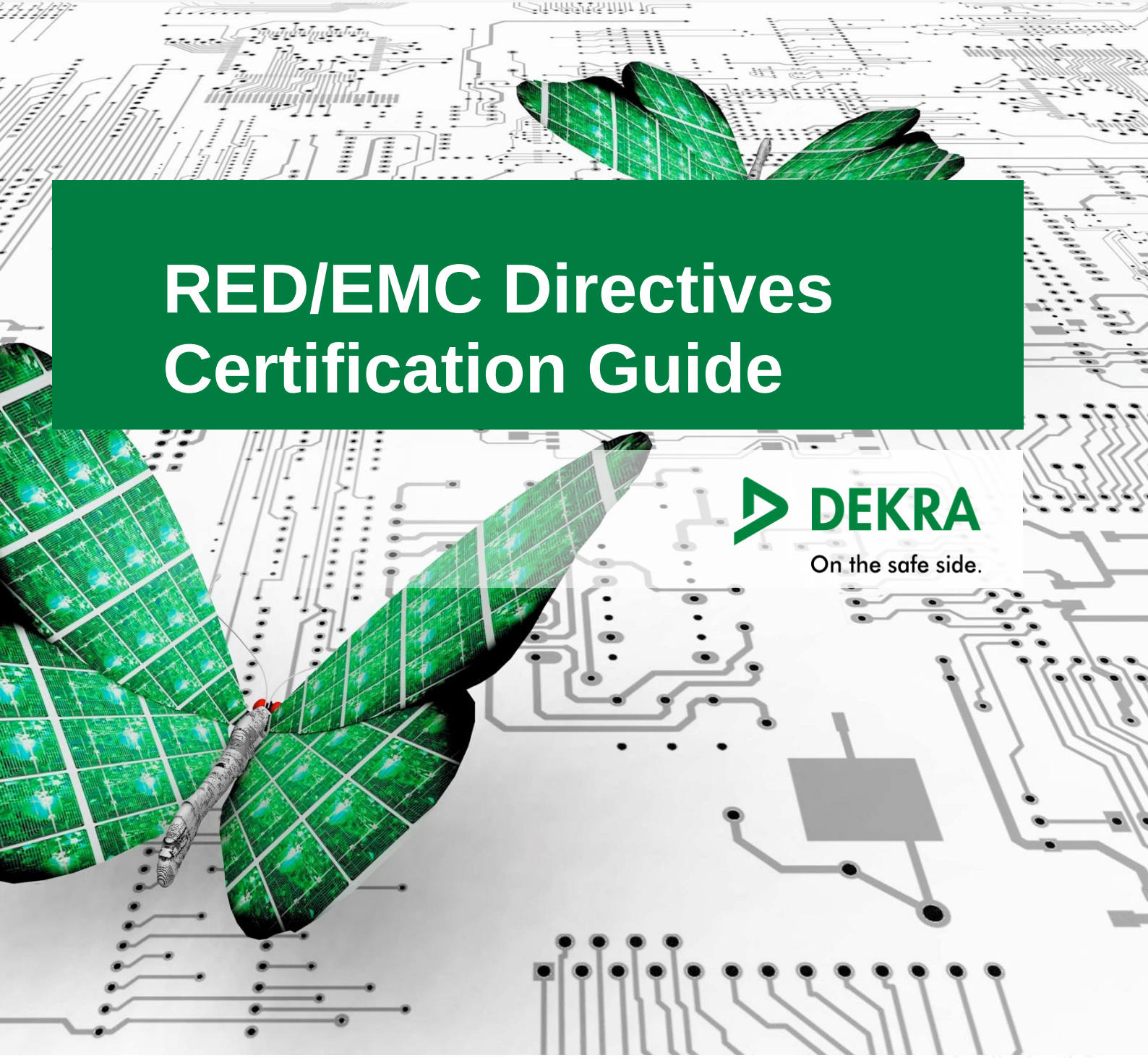

RED/EMC Directives Certification Guide

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 RED or EMC certification by contacting your DEKRA Account Manager or by writing to: infolab.es@dekra.com.

Please include in your request the technical specifications of the device, the intended scope of certification (RED or EMC Directive), and any additional services you may require (e.g. testing).

Once your request is received, DEKRA will assign an Account Manager who will contact you to clarify any details and provide a service offer.

Initiating the certification process

Once you have accepted the service offer and are ready to proceed with the certification process through the Notified Body, please inform us by sending an email to certification.rcb.es@dekra.com, indicating that you are prepared to submit the documentation package (see list of documentation in section 4).

Upon receiving your message, DEKRA will provide detailed instructions for submitting the technical documentation. Depending on your case, you will be invited to use one of the following options:

- A secure link to DEKRA's platform **SolutionPRO Certification**, where you can upload the required documentation, track the progress of your evaluation, and access your certificates (preferred option)
- By setting up an FTP account to which DEKRA can access
- By email (in case of small-sized documentation)

Once the documentation is received, the Certification Body will assign a reviewing engineer who will act as your main point of contact throughout the evaluation.

The manufacturer shall lodge an application for EU-type examination only with a single Notified Body of their 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/modifications to an existing EU-type examination certificate

Since "Family" or "System" certification is not explicitly defined in Directive 2014/53/EU (RED) or Directive 2014/30/EU (EMC), the acceptance of multiple devices under a single EU-Type Examination Certificate relies on the criteria of the Notified Body.

To determine the applicable certification approach, DEKRA applies the following definitions:

- Product Variant or Modification: a product variant is a new model added to an existing EU-TEC family based on the same core design, while a product modification is an update to an already certified model where hardware or software changes may affect performance but do not create a new product.
- Family/System: a certification covering multiple models that are similar in function, appearance, and design, or that belong to a system of devices that interact together.

The acceptance of models as a family is evaluated on a case-by-case basis. The essential premise for this approval is that every model included in the certificate must be evaluated, and evidence of compliance with the essential requirements must be provided for all of them

4. Required documentation

The documentation to be submitted depends on the scope of your application.

- Go to **Section 4.1** if your application under the RED covers Articles 3.1(a), 3.1(b), 3.2, and possibly also 3.3(d), (e) or (f).
- Go to **Section 4.2** if your application is exclusively limited to RED Article 3.3(d), (e) or (f) (cybersecurity).
- Go to **Section 4.3** if your application is made under the EMC Directive.

General principles

Technical documentation must demonstrate how compliance with the essential requirements is achieved:

- For RED: Article 3 of the Radio Equipment Directive.
- For EMC Directive: Annex II of the EMC Directive.

Documentation must be prepared before placing equipment on the market and kept continuously updated.

Documentation and correspondence must be in an official language of the Member State where the Notified Body is established, or in another language accepted by the Notified Body.

4.1. RED Applications for Articles 3.1, 3.2 and optionally 3.3

This section applies to RED EU-type examination applications covering Articles 3.1 (a), 3.1 (b), 3.2 and optionally 3.3 (d), (e), or (f) of the RED. If your application is limited only to cybersecurity Article 3.3 (d), (e), or (f), see section 4.2 for a reduced documentation set.

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).

Item #	Document	Description	When required	
			Original / Family Parent	Family children/ Variant / Modification models
1. Regulatory Documentation		*Required for identifying the applicant, the product and meeting legal obligations related to the application*		
1.1.	RED form	Formal document identifying the product, applicant and the requested scope (RED articles). **Form FCB023** can be used (available on www.dekra-product-safety.com/wireless)	**Required**	**Required**
1.2.	Authorisation Letter	A signed letter allowing a third-party agent to act on behalf of the applicant/manufacturer	Only if agent is used	Only if agent is used
1.3.	RED Annex V declaration	Declaration explaining compliance with Art. 10(2) and packaging information required by Art. 10(10). **Form FCB038** can be used (available on www.dekra-product-safety.com/wireless)	**Required**	Only if different from the original
1.4.	EU DoC	Draft or final version of the EU DoC are both acceptable. The DoC must be part of the Technical Documentation at manufacturer side, but it is not mandatory to submit it to the Notified Body	Optional	Optional
2. Risk & Change management		*Documents to assess the risk analysis, confirm equivalence of family/variant models and validate original evaluation after changes*		
2.1.	Risk Assessment	Document analyzing possible risks (RF, electrical, EMC, EMF, cybersecurity) and how they are mitigated to comply with applicable standards	**Required**	Only if different from the original
2.2.	Family / Variant / Modification Changes Declaration	Documents enabling the Notified Body to confirm equivalence of family or variant models to the original, and thus the validity of original evaluation results: - **Changes Declaration:** signed statement listing all HW, SW/FW, feature, interface, or enclosure differences between the reference device and each variant. It shall include a description of modifications with emphasis on (i) RF frequency and output power, (ii) RF circuitry, and (iii) functional capabilities; including a separate description of software changes addressing the same three aspects - **Equivalence Technical Justification:** explanation why these differences do not affect compliance or evaluation results - **Evidence:** reference to supporting docs provided through documents requested later in this guide (e.g., internal/external photos, schematics, hardware diagrams).	N/A	**Required**
2.3.	Tested Sample vs. Final Product Changes	Document describing any HW/SW differences between the specific sample tested/audited and the final commercial version. Must justify why test results remain valid	Only if the final product is not identical to the tested sample	

Item #	Document	Description	When required	
			Original / Family Parent	Family children/ Variant / Modification models
3. Technical documentation		*Required to verify the device identity, ensure the certified product matches the description/test sample and that the evaluation is based on the correct configuration*		
3.1.	Technical Specifications	A document explaining what the device is, how it operates and the intended use. In addition, it shall contain: - RF parameters: radio technologies supported, frequency bands, modulations, duty cycle, output power, etc…) - Power supply and other relevant system-level info - HW & SW architecture - External wireless/wired interfaces and ports - Supported protocols & Security-relevant features	**Required**	Only if different from the original
3.2.	Antenna specifications	Specifications, datasheet, gain and other relevant details of the antenna(s) used with the device. This information may be combined with the Technical Specifications (Item 3.1).	**Required**	Only if different from the original
3.3.	Tune up info	For cellular devices (2G/3G/4G/5G)	**Required** for cellular	Only if different from the original
3.4.	User's guide	A copy of the installation and operating instructions to be furnished the user including all regulatory notices	**Required**	Only if different from the original
3.5.	Block diagram	A block diagram showing the frequency of all oscillators in the device. The signal path, frequencies and intermediate frequencies shall be indicated at each block.	**Required**	For product families, the applicant/ manufacturer must submit only the evidence needed to demonstrate equivalence. Full sets of technical documents for every model are not mandatory.
3.6.	Schematics	Electrical diagrams Schematics of each Printed Circuit Board (PCB) of the device, indicating location of radio chipset.	**Required**	
3.7.	Mechanical diagrams	Diagrams of the Printed Circuit Board (PCB) layout showing the paths connecting electronic components and their placement. Component placement can be provided in a separate document.	**Required**	
3.8.	Bill of materials (BOM)	List of components, especially those affecting compliance (MCU, radio chips, memory, passive components, etc…).	**Required**	
3.9.	Photographs (internal/External)	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. 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.	**Required**	
3.10.	Electrical safety test report	Test report showing compliance with electrical safety essential requirement (Art. 3.1(a))	**Required** if applicable	Only if different from the original
3.11.	EMF exposure test report/calculation	SAR report/MPE calculation showing compliance with health (EMF exposure) essential requirement (Art. 3.1(a))	**Required** if applicable	Only if different from the original
3.12.	EMC test report	EMC test report showing compliance with EMC essential requirement (Art. 3.1(b))	**Required** if applicable	Only if different from the original
3.13.	RF test report	RF test report showing compliance with efficient radio spectrum use essential requirements (Art. 3.2)	**Required** if applicable	Only if different from the original
3.14.	Cyber security test report	Test report showing compliance with essential requirements against Art. 3.3 (d), (e) and/or (f). NOTE: If the test report does not include intake form, it is required to provide it separately.	**Required** if applicable	Only if different from the original

Item #	Document	Description	When required	
			Original / Family Parent	Family children/ Variant / Modification models
4. Module integration		*If a module is integrated, the NB needs to understand its structure, functions, interfaces, components, and potential cybersecurity impacts*		
4.1.	Module documentation	Includes block diagram, technical description, schematics, mechanical diagrams, bill of materials and test reports of the module. If the host manufacturer cannot access proprietary module data, the module manufacturer must send it directly to the NB. Lack of this documentation may prevent the NB from issuing an opinion on the TCF.	**Required** when the device integrates a module. **Not required** if the Module EU-TEC is provided.	

4.2. RED applications limited to Cybersecurity, Article 3.3 (d), (e) and/or (f)

This section applies to applications exclusively limited to Article 3.3 (d), (e) and (f). Although documentation is typically reduced in these cases, the final set depends on the device features and assessment scope. Documents related to radio functionality (e.g., RF test reports, DoC) must be maintained in the manufacturer's technical documentation but are not submitted to the Notified Body unless specifically requested.

To identify the applicable requirements in the table below, please classify your application as follows:

- Original: a new device that has not been previously certified.
- Product Variant or Modification: a new model added to an existing EU-TEC family (variant) or an update to a certified model with HW/SW changes (modification), both based on the same core design.
- Family: a group of models that are similar in function, appearance, and design, or belong to a system of interacting devices. All models must be technically equivalent regarding cybersecurity risks

Item #	Document	Description	When required	
			Original / Family Parent	Family children/ Variant / Modification models
1. Regulatory Documentation		*Required for identifying the applicant, the product and meeting legal obligations related to the application*		
1.1.	RED form	Formal document identifying the product, applicant and the requested scope (RED-DA articles). **Form FCB023** can be used (available on www.dekra-product-safety.com/wireless)	**Required**	**Required**
1.2.	Authorisation Letter	A signed letter allowing a third-party agent to act on behalf of the applicant/manufacturer	Only if agent is used	Only if agent is used
1.3.	RED Annex V declaration	Declaration explaining compliance with Art. 10(2) and packaging information required by Art. 10(10). **Form FCB038** can be used (available on www.dekra-product-safety.com/wireless)	**Required**	Only if different from the original
2. Risk & Change management		*Documents to assess the risk analysis, confirm equivalence of family/variant models and validate original evaluation after changes*		
2.1.	Risk Assessment	A document identifying cybersecurity risks related to the device, how they were evaluated and how they are mitigated to comply with applicable standards	**Required**	Only if different from the original
2.2.	Family / Variant Changes Declaration	Documents enabling the Notified Body to confirm equivalence of family or variant models to the original, and thus the validity of original cybersecurity evaluation results: **Changes Declaration:** a signed statement listing all differences between the reference device and each variant (HW, SW/FW, features, interfaces, enclosure changes, etc.). **Equivalence Technical Justification:** explanation why these differences do not affect cybersecurity compliance or evaluation results **Evidence:** reference to supporting docs provided through documents requested later in this guide (e.g., internal/external photos, schematics, hardware diagrams).	N/A	**Required**
2.3.	Tested Sample vs. Final Product Changes	Document describing any HW/SW differences between the specific sample tested/audited and the final commercial version. Must justify why test results remain valid	Only if the final product is not identical to the tested sample	

Item #	Document	Description	When required	
			Original / Family Parent	Family children/ Variant / Modification models
3. Technical documentation		*Required to verify the device identity, ensure the certified product matches the description/test sample and that the evaluation is based on the correct configuration*		
3.1.	Technical Specifications	A document explaining what the device is, how it operates and the intended use. In addition, it usually contains: - Power supply - Radio technologies supported & Frequency bands - HW & SW architecture - External wireless/wired interfaces and ports - Supported protocols & Security-relevant features Must give enough detail to understand the attack surface and the cybersecurity-relevant behavior of the device.	**Required**	Only if different from the original
3.2.	Antenna specifications	Identification of the antennas, number and internal/external use. This information may be combined with the Technical Specifications (Item 3.1).	**Required**	Only if different from the original
3.3.	User's guide	A copy of the installation and operating instructions to be furnished the user including all regulatory notices	**Required**	Only if different from the original
3.4.	Block diagram	A functional block diagram showing key subsystems relevant to cybersecurity (MCU, connectivity chips, memory, interfaces, etc.).	**Required**	For product families, the applicant/ manufacturer must submit only the evidence needed to demonstrate equivalence. Full sets of technical documents for every model are not mandatory.
3.5.	Schematics	Electrical diagrams Schematics of each Printed Circuit Board (PCB) of the device, indicating location of radio chipset. These are necessary to verify secure element integration and hardware interfaces (e.g. chipset model matches technical specifications)	**Required**	
3.6.	Mechanical diagrams	Diagrams of the Printed Circuit Board (PCB) layout showing the paths connecting electronic components and their placement. Component placement can be provided in a separate document.	**Required**	
3.7.	Bill of materials (BOM)	List of components, especially those affecting cybersecurity (MCU, radio chips, memory, passive components, etc…).	**Required**	
3.8.	Photographs (internal/External)	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. External photographs of the enclosure from all views, ports and labelling.	**Required**	
3.9.	Cyber security test report	Test report showing compliance with essential requirements against articles 3.3 (d), (e) and/or (f). NOTE: If the test report does not include intake form, it is required to provide it separately.	**Required**	Only if different from the original

4.3. EMC Directive type of applications

This section applies to applications under the **EMC Directive**

Item #	Document	Description	When required	
			Original / Family Parent	Family children/ Variant / Modification models
1. Regulatory Documentation		*Required for identifying the applicant, the product and meeting legal obligations related to the application*		
1.1.	Application form	Formal document including equipment, applicant, manufacturer, TCF and standards information. **Form FCB024** can be used (available on www.dekra-product-safety.com/wireless)	**Required**	**Required**
1.2.	Authorisation Letter	A signed letter allowing a third-party agent to act on behalf of the applicant/manufacturer	Only if agent is used	Only if agent is used
2. Risk & Change management		*Documents to assess the risk analysis, confirm equivalence of family/variant models and validate original evaluation after changes*		
2.1.	Risk Assessment	A risk assessment analyzing the possible risks and demonstrating how they are reduced to comply with the essential requirements	**Required**	Only if different from the original
2.2.	Family / Variant Changes Declaration	Documents enabling the Notified Body to confirm equivalence of family or variant models to the original, and thus the validity of original evaluation results: - **Changes Declaration:** signed statement listing all HW, SW/FW, feature, interface, or enclosure differences between the reference device and each variant, with emphasis on: o digital devices circuitry o crystal, clocks and PCB changes o power supply circuitry and components o accessible ports o functional capabilities o firmware of digital devices included in the product (e.g. microprocessors, I/O signal processors,..) - **Equivalence Technical Justification:** explanation why these differences do not affect compliance or evaluation results - **Evidence:** reference to supporting docs provided through documents requested later in this guide (e.g., internal/external photos, schematics, hardware diagrams).	N/A	**Required**
2.3.	Tested Sample vs. Final Product Changes	Document describing any HW/SW differences between the specific sample tested/audited and the final commercial version. Must justify why test results remain valid	Only if the final product is not identical to the tested sample	

Item #	Document	Description	When required	
			Original / Family Parent	Family children/ Variant / Modification models
3. Technical documentation		*Required to verify the device identity, ensure the certified product matches the description/test sample and that the evaluation is based on the correct configuration*		
3.1.	Technical Specifications	A document explaining what the device is, how it operates and the intended use. In addition, it shall contain: - RF parameters: radio technologies supported, frequency bands, modulations, duty cycle, output power, etc…) - Power supply and other relevant system-level info - HW & SW architecture - External wireless/wired interfaces and ports	**Required**	Only if different from the original
3.2.	User's guide	A copy of the installation and operating instructions to be furnished the user including all regulatory notices	**Required**	Only if different from the original
3.3.	Block diagram	A block diagram showing the frequency of all oscillators in the device. The signal path, frequencies and intermediate frequencies shall be indicated at each block.	**Required**	For product families, the applicant/ manufacturer must submit only the evidence needed to demonstrate equivalence. Full sets of technical documents for every model are not mandatory.
3.4.	Schematics	Electrical diagrams Schematics of each Printed Circuit Board (PCB) of the device, indicating location of radio chipset.	**Required**	
3.5.	Mechanical diagrams	Diagrams of the Printed Circuit Board (PCB) layout showing the paths connecting electronic components and their placement. Component placement can be provided in a separate document.	**Required**	
3.6.	Bill of materials (BOM)	List of components, especially those affecting compliance (MCU, radio chips, memory, passive components, etc…).	**Required**	
3.7.	Photographs (internal/External)	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. External photographs of the enclosure from all views, ports and labelling.	**Required**	
3.8.	Label design	Including: brand name, model name, CE marking, etc.	**Required**	Only if different from the original
3.9.	EMC test report	EMC test report showing compliance with EMC essential requirement (Art. 3.1(b))		

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.

Revision History

Reference	Issue date	Changes
FCB033_02	07/4/2017	Update of Company name references.
FCB033_03	18/09/2017	Addition of History of changes.
FCB033_04	06/09/2019	Update of chapter “Disclosure of information” to include the possibility of access to the information by the Impartiality Committee or by the accreditation body.
FCB033_05	01/07/2020	Update of section 4.
FCB033_06	05/11/2021	Update of section 3.3.
FCB033_07	24/05/2022	Update of section 3.3.
FCB033_08	29/09/2023	Update of technical documentation required for EMC directive.
FCB033_09	10/07/2024	Update of technical document required for RE-Directive.
FCB033_10	22/11/2025	Update of section 2.1 (application process) and section 4 (documentation requirements), including specific chapter for applications limited to Art. 3.3(d/e/f). Editorial changes.