European Union

The European Radio Equipment Directive 2014/53/EU

All items of equipment within its scope placed on the European Market for the first time must follow one of the RED Conformity Assessment Procedures.

In order to be legally used in the European market equipment must comply with the requirements of the Directive when first used.
Approach

• The general principles for product compliance in the Radio Equipment Directive are very similar to the R&TTE Directive:
  – Compliance with a set of essential requirements:
    ▪ Article 3.1(a) Health and safety
    ▪ Article 3.1(b) EMC
    ▪ Article 3.2 Radio
    ▪ Article 3.3 additional requirements when invoked by the European Commission
  – Harmonised standards provide a presumption of conformity with the essential requirements
  – Conformity assessment procedures:
    ▪ Internal Production Control
    ▪ Assessment of technical documentation by a Notified Body (Type Examination)
    ▪ Full Quality Assurance Approval
  – Use of a Notified Body where no radio or Article 3.3 Harmonised Standard exists
• However, there are some major changes and manufacturers, authorised representatives, importers and distributors (and Notified Bodies and Market Surveillance Authorities) need to be ready for when the Directive is fully in place
• Radio receivers must achieve a minimum level of performance to contribute to an efficient use of radio spectrum (includes broadcast radio and TV receivers)
• Fixed line terminal equipment is outside the scope of the RED
• Clear obligations for manufacturers, importers and distributors
• Strengthened market surveillance, e.g., the traceability obligations of manufacturers, importers and distributors
• Notified Body Opinion of Annex IV of R&TTE Directive replaced by Type Examination procedure where modifications to products which affect compliance must be agreed by the Notified Body
• Product registration scheme for types of radio equipment within categories affected by low levels of compliance (determined by European Commission)
Key Changes (2)

- Deletion of notification procedure for radio equipment using non-harmonised frequency bands
- Deletion of “alert” mark
- No requirement for CE marking in user documentation
- Deletion of the R&TTE Directive Annex III procedure
- Explicit requirements for combinations of radio equipment and software
- Technical documentation includes confirmation of operation in at least one Member State without infringing requirements on the use of radio spectrum
- Cannot use the EMC Directive or LVD conformity assessment procedures, the RED only refers to the EMC Directive and LVD to state the essential EMC and Health & Safety requirements
Key Changes (3)

- Interworking with accessories such as common chargers can be invoked under Article 3.3 if decided by the European Commission.
- Sample testing of products by manufacturer / importer to protect the health and safety of end users; plus register of complaints and recalls.
- Electronic CE marking not permitted but is included for review by Commission.
- Notified Body identification number must not be used in the CE marking on products which followed the Type Examination procedure.
- CE + NB number product marking only for Annex IV FQA.
- NB number must be used in DoC where Type Examination or FQA procedure is followed.
- User information for radio transmitters should include:
  - 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.
Current Status of the RED

• After several years of drafting and national consultations, draft issued October 2012, IMCO report issued October 2013
• A compromise text was produced in January 2014
• Text adopted at its first reading by the European Parliament in March 2014
• Statement from the EU Commission, March 2014:
  – “the Commission has decided not to stand in the way of a final agreement”
  – with an abstention from the UK – “The UK is unable to support the final agreed text on the Radio Equipment Directive. The text contains the possibility to require, through a Delegated Act, registration of product types where there is a low level of compliance”
• Text adopted by the EU Council on 14th April
• Publication in the Official Journal on 22nd May 2014 as Directive 2014/53/EU
RED Transition

- The Radio Equipment Directive
  - Published in the Official Journal on 22\textsuperscript{nd} May 2014
  - The obligation is on Member States to adopt and publish in national law by 12 June 2016; and apply the RED from 13 June 2016
  - The R&TTE Directive 1999/5/EC is repealed from 13 June 2016
  - Products previously assessed and with a Declaration of Conformity against R&TTE Directive 99/5/EC issued before 13 June 2016 may continue to be placed on the market until 13 June 2017
  - A “making available on the market” and “putting into service” provision means that products that comply with the R&TTE Directive before 13 June 2016 and are placed on the market before 13 June 2017 may be sold and brought into service later (Article 48)
Scope of RED

- Products which fit within the following definitions (and are not excluded by Article 1 – see later) are subject to the RED:
  - 'radio equipment' means 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
  - 'radio communication' means communication by means of radio waves
  - 'radiodetermination' means the determination of the position, velocity and/or other characteristics of an object, or the obtaining of information relating to those parameters, by means of the propagation properties of radio waves
  - 'radio waves' means electromagnetic waves of frequencies lower than 3000 GHz, propagated in space without artificial guide

Note: equipment which makes use of radio waves without radio communication or radiodetermination is outside of the scope of the RED, e.g. microwave ovens
Scope of RED

• All radio receivers, including broadcast radio and TV receivers, (apart from those excluded by Article 1) are within the scope of the RED. Justification provided by the European Parliament’s Committee on the Internal Market and Consumer Protection:
  – considering that radio spectrum is a finite resource, it is important to guarantee its efficient usage, therefore the equipment capable of receiving radio waves should fall under the scope of proposed Directive.

• Telecommunications Terminal Equipment (TTE), i.e. fixed line terminal equipment, is outside the scope of the RED and, as a result, is within the scope of the EMC Directive and LVD
Scope of RED - exclusions

- “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 used by radio amateurs within the meaning of Article 1, definition 56, of the International Telecommunications Union (ITU) Radio Regulations, unless the equipment is made available on the market.
  - The following shall be regarded as not being made available on the market:
    - (a) radio kits for assembly and use by radio amateurs;
    - (b) radio equipment modified by and for the use of radio amateurs;
    - (c) equipment constructed by individual radio amateurs for experimental and scientific purposes related to amateur radio.
- Marine equipment falling within the scope of Council Directive 96/98/EC
- Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes
### Examples of Equipment Types included in the RED

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<th>Equipment Type</th>
<th>Description</th>
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RED Essential Requirements

The technical requirement is that equipment within the scope of the Directive must comply with the “Essential Requirements”

Definition of “Essential Requirements” is given in Article 3 of the Directive:

| Essential Requirements | 3.1(a) Health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in LVD, but with no voltage limit applying *Includes all hazards, such as SAR/RF exposure and Acoustic Shock | 3.1(b) EMC An adequate level of electromagnetic compatibility as set out in EMC Directive | 3.2 Effective use and support the efficient use of radio spectrum in order to avoid harmful interference | 3.3 Additional requirements where decided by European Commission: |

Note: BABT would have concerns certifying products that risk the health & safety of any animal, not just domestic animals.
• Radio equipment within certain categories or classes shall be so constructed that it complies with the following essential requirements:
  (a) radio equipment interworks with accessories, in particular with common chargers
  (b) radio equipment interworks via networks with other radio equipment;
  (c) radio equipment can be connected to interfaces of the appropriate type throughout the Union
  (d) radio equipment does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service
  (e) radio equipment incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected
  (f) radio equipment supports certain features ensuring protection from fraud
  (g) radio equipment supports certain features ensuring access to emergency services
  (h) radio equipment supports certain features in order to facilitate its use by users with a disability
  (i) radio equipment supports certain features in order to ensure that software can only be loaded into the radio equipment where the compliance of the combination of the radio equipment and software has been demonstrated

• The Commission can determine which categories or classes of radio equipment are covered by each of the requirements set out in points (a) to (i)
• Manufacturers shall provide the Member States and the Commission with information on the compliance of intended combinations of radio equipment and software with the essential requirements.
  – Such information shall result from a conformity assessment, and shall be given in the form of a statement of compliance which includes the elements set out in Annex VI (the DoC).
  – Depending on the specific combinations of radio equipment and software, the information shall precisely identify the radio equipment and the software which have been assessed, and it shall be continuously updated.

• The Commission can determine which categories or classes of radio equipment are covered by this requirement
• From 12 June 2018, manufacturers must register radio equipment types within categories of radio equipment affected by a low level of compliance with the essential requirements within a central system before being placed on the market.

• The Commission can determine which categories of radio equipment are covered by this requirement; and which technical documentation must be provided.

• The Commission will specify the operational rules for registration and the operational rules for affixing the registration number on radio equipment for the categories specified.

• The Commission will make available a central system allowing manufacturers to register the required information with appropriate control of access to confidential information.
At trade fairs, exhibitions and similar events (Article 9)

- Radio equipment which does not comply with this Directive may be displayed, provided that a visible sign clearly indicates that such radio equipment may not be made available on the market or put into service until it has been brought into conformity with this Directive.
- Demonstration of radio equipment may only take place provided that adequate measures, as prescribed by Member States, have been taken to avoid harmful interference, electromagnetic disturbances and risk to the health or safety of persons or of domestic animals or to property.
“Harmonised Standard”

- Article 16 of the RED
- Use of appropriate harmonised standard(s) referenced in the Official Journal of the European Communities gives an automatic presumption of conformity with the particular essential requirements of the Directive for which it has been listed, providing legal protection for the manufacturer
Definition of Essential Requirements

Conformity Assessment Procedure based on compliance with Essential Requirements

**Compliance is against Essential Requirements, not standards.** However, compliance with appropriate “Harmonised Standards” gives an automatic presumption of conformity with the appropriate Essential Requirements. There does not need to be a “Harmonised Standard” to apply one of the Conformity Assessment Procedures. The Essential Requirements apply even in the absence of harmonised standards.
• The manufacturer shall perform a conformity assessment of the radio equipment with a view to meeting the essential requirements
• Conformity assessment shall take into account all intended operating conditions and, for the Article 3(1)(a) essential requirement (Health & Safety), the assessment shall also take into account the reasonably foreseeable conditions.
• Where the radio equipment is capable of taking different configurations, the conformity assessment shall confirm whether the radio equipment meets the essential requirements in all possible configurations.
Conformity Assessment Procedures (Article 10 R&TTE Directive)

Current R&TTE Directive Procedure:

- Non radio Terminal Equipment and receive only radio equipment
  - Annex II Internal Production Control

- Radio transmitting equipment (not using or partial use of harmonised standards)
  - Annex III Internal Production Control plus specific tests
  - Annex IV Technical Construction File

- Radio transmitting equipment (using harmonised standards)
  - Annex V Full Quality Assurance
RED Conformity Assessment Procedures (Article 17)

Radio Equipment Directive
Market Surveillance

• Market surveillance remains a national responsibility
• Market surveillance procedure for dealing with risk to Health & Safety and non-compliance with the essential requirements in Article 40, 41 and 42
• Article 43 requires the relevant economic operator to correct:
  – Non-compliant or no CE marking
  – Non-compliant or no notified Body identification number when Annex IV FQA is used
  – Non-compliant or no DoC
  – Technical documentation not available or not complete
  – Absent, false or incomplete type name, batch/serial number, manufacturer or importer name
  – Intended use information, DoC or usage restrictions not supplied with radio equipment
  – Identification of economic operators not supplied
  – Non-compliance with the registration procedure where required
• Persistent non-compliance with Article 43 can result in market withdrawal or recall
Economic Operators

- Manufacturers (both inside and outside Europe) – Article 10
- Authorised Representative (in Europe) – Article 11
- Importers (in Europe) – Article 12
- Distributors (in Europe) – Article 13
Manufacturers’ Responsibilities (1)

- Design and manufacturer product to meet the Essential Requirements of RED
- Ensure that radio equipment can be operated in at least one member state without infringing applicable requirements on use of radio spectrum
- Establish compliance through test (and justification) and compilation of compliance documentation and carry out the relevant Conformity Assessment Procedure
- Write Declaration of Conformity and apply CE mark
- Retain compliance documentation for at least 10 years after the last item of the apparatus has been manufactured
- Define the manufacturing process to ensure all individual items of the product comply with the RED – changes in product design and harmonised standards should be taken into account
- When deemed appropriate to protect Health & safety of end users, carry out sample testing; investigate and keep a register of complaints of non-conforming radio equipment and radio equipment recalls; and keep distributors informed
- Make compliance documentation available to surveillance authorities on request in a language easily understood by that authority
Manufacturers’ Responsibilities (2)

- Radio equipment bears type, batch/serial number; or because of size or nature of radio equipment, on packaging or documentation
- Manufacturer’s name and postal address; or because of size or nature of radio equipment, on packaging or documentation. Single point address required
- Radio equipment to be accompanied by instructions and safety information which can be easily understood by consumers and other end-users
- 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.
- Information shall also be included for transmitting radio equipment:
  - 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
Manufacturers’ Responsibilities (3)

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

• For restrictions on putting into service or of requirements for authorisation of use (licensing), information 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 authorisation of use exist. Such information shall be included in the user instructions.

• If a manufacturers believes that radio equipment is not in conformity with the RED shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Where the radio equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market to that effect, giving details, in particular, of the non-compliance, of any corrective measures taken and of the results.
Authorised Representatives’ Responsibilities

• A manufacturer may, by a written mandate, appoint an authorised representative.
• The manufacturer’s obligations to design and manufacture product to meet the Essential Requirements of RED and the obligation to draw up technical documentation shall not form part of the authorised representative's mandate.
• An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
  – keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the radio equipment has been placed on the market
  – further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of radio equipment
  – cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by radio equipment covered by the authorised representative's mandate.
Importers’ Responsibilities (1)

- Importers shall place only compliant radio equipment on the market.
- Before placing radio equipment on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer and that the radio equipment is so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum. They shall ensure that the manufacturer has drawn up the technical documentation, that the radio equipment bears the CE marking and is accompanied by the appropriate information and documents, and that the manufacturer has complied with the requirements set out in Article 10(6) (type, batch/serial number) and 10(7) (manufacturer’s name and single point postal address).
- Indicate on the radio equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the radio equipment. This includes cases where the size of radio equipment does not allow it, or where importers would have to open the packaging in order to indicate their name and address on the radio equipment.
Importers’ Responsibilities (2)

- Importers shall ensure that the radio equipment is 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.
- Importers shall ensure that, while radio equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements.
- When deemed appropriate to protect the health and safety of end-users; carry out sample testing; investigate, and keep a register of complaints of non-conforming radio equipment and radio equipment recalls; and keep distributors informed.
Importers’ Responsibilities (3)

• Importers who believe that radio equipment which they have placed on the market is not in conformity with the RED shall follow the procedure of Article 12(7)
• For 10 years after the radio equipment has been placed on the market, keep a copy of the DoC and ensure that the technical documentation can be made available to authorities upon request
• Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of radio equipment in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market
• Persons purchasing products over the internet from manufacturers outside Europe assume the responsibility of the importer
Distributors’ Responsibilities (1)

- Distributors shall act with due care in relation to the requirements of the RED.
- Verify that the radio equipment bears the CE marking, that it is accompanied by the required documentation and instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the radio equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 10(2) and (6) to (10) and Article 12(3) respectively.
- If a distributor believes that radio equipment is not in conformity with the essential requirements, he shall not make the radio equipment available on the market until it has been brought into conformity. Furthermore, where the radio equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.
- Ensure that storage or transport conditions do not jeopardise its compliance with the essential requirements.
Distributors’ Responsibilities (2)

- Distributors who believe that radio equipment they have supplied is not in conformity with the RED shall follow the procedure of Article 13(4)
- Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of radio equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have made available on the market.
Importers and Distributors (Article 14)

- An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 10, where he places radio equipment on the market under his name or trade mark or modifies radio equipment already placed on the market in such a way that compliance with this Directive may be affected.

Note: this means that if an importer or distributor markets a product under their own name or brand then they assume the responsibilities of the manufacturer, e.g. a chain store importing equipment and selling it under their own name or brand.
• Economic operators shall, on request, identify the following to the market surveillance authorities:
  – any economic operator who has supplied them with radio equipment;
  – any economic operator to whom they have 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.
Conformity Assessment Procedures

- Annex II – Internal Production Control – no Notified Body involvement, a self declaration procedure
- Annex III – EU Type Examination and Conformity to Type based on Internal Production Control - Notified Body involvement to assess the technical documentation
- Annex IV – Full Quality Assurance - Notified Body involvement to assess design, manufacturing, inspection and test processes
Annex II – Internal Production Control

- Prepare the technical documentation in accordance with Article 21
- The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance with the technical documentation and with the essential requirements of the RED
- Affix CE marking to each item of radio equipment that satisfies the applicable requirements of this Directive.
- Draw up a written declaration of conformity (DoC) for each radio equipment type and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.
- A copy of the DoC available to the relevant authorities upon request
- The manufacturer's obligations for CE marking and the DoC may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
Annex III – EU Type Examination and Conformity to Type based on Internal Production Control (1)

- Prepare the technical documentation in accordance with Article 21
- Manufacturer submits application to a single notified body of his choice
- The notified body examines the technical documentation and supporting evidence to assess compliance with the RED. If compliant, issues an **EU Type Examination Certificate**
- The notified body must maintain its technical knowledge to be able to determine that a certified type may no longer comply with the applicable requirements of the Directive, and determine whether such changes require further investigation. If so, the notified body must inform the manufacturer
- The manufacturer must inform the notified body of all modifications to the product that may affect compliance with the essential requirements or the conditions for validity of the Type Examination certificate
- The manufacturer must keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.
Annex III – EU Type Examination and Conformity to Type based on Internal Production Control (2)

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

• Affix CE marking to each item of radio equipment that satisfies the applicable requirements of the RED.

• Draw up a written declaration of conformity (DoC) for each radio equipment type and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market.

• A copy of the DoC must be available to the relevant authorities upon request.

• The manufacturer's obligations for CE marking and the DoC may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.
Annex IV – Full Quality Assurance

• FQA Approval is an approval of the manufacturer’s processes which permits the application of the CE mark to products within the scope of the FQA

• Manufacturer submits an FQA application to a single notified body of his choice which includes a sample set of technical documentation for each product type

• The quality system must ensure compliance of the radio equipment with the requirements of the Directive

• Manufacturer requirements:
  – must operate approved processes for design, manufacture and final testing
  – the processes must ensure compliance of the products
  – lodge an application for the assessment of his quality system with NB
  – must allow NB access to audit design, manufacture, inspection, test and storage areas and provide necessary information on the quality system records

• Quality systems based upon ISO9000 and test facilities operating to ISO17025 inherently meet many but not necessarily all of the requirements for FQA Approval under the Directive

• The notified body assesses the quality system by periodic audits to determine whether it satisfies the requirements of Annex IV of the Directive
Technical documentation (Article 21)

- Shall contain all relevant data or details of the means used by the manufacturer to ensure that radio equipment complies with the essential requirements
- Technical documentation shall be drawn up before radio equipment is placed on the market and shall be continuously updated.
- 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.
- Where the technical documentation does not comply, the market surveillance authority may ask the manufacturer or the importer to have a test performed by a body acceptable to the market surveillance authority at the expense of the manufacturer or the importer within a specified period in order to verify compliance with the essential requirements.

Note: continuously updated – as a minimum, we would expect technical documentation to be updated when the product or standard has changed.
• A general description of the radio equipment including: photographs or illustrations, versions of software or firmware affecting compliance with essential requirements, user information and installation instructions
• Conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits and other relevant similar elements
• Descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the radio equipment
• List of OJ listed harmonised standards used, and, where harmonised standards have not been applied, the solutions used to meet essential requirements
• DoC
• Where Annex III has been applied, a copy of the EU-type examination certificate
• Results of design calculations, examinations carried out
• Test reports
• An explanation of operation in at least one Member State without infringing requirements on the use of radio spectrum and of the inclusion or not of information on the packaging
EU Declaration of Conformity (DoC) (Article 18)

- DoC states that compliance with the essential requirements has been demonstrated
- Have the structure set out in Annex VI
- Be continuously updated
- Translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market.
- Where radio equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts
  - In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity. (Recital 42)
Contents of DoC (Annex VI)

- Radio equipment (product, type, batch or serial number):
- Name and address of the manufacturer or his authorised representative:
- Declaration of conformity is issued under the sole responsibility of manufacturer.
- Object of the declaration (identification of the radio equipment allowing traceability; it may include a colour image of sufficient clarity for identification)
- Object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
  - Radio Equipment Directive 2014/.../EU
  - Other Union harmonisation legislation where applicable
- References to the relevant harmonised standards and versions used or references to the other technical specifications to which conformity is declared.
- Where applicable, the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the EU-type examination certificate: ...
- Description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the DoC
Simplified DoC (Annex VII)

• Where a simplified DoC is provided it shall be provided as follows:
  – Hereby, [Name of manufacturer] declares that the radio equipment type [designation of type of radio equipment] is in compliance with Directive 2014/.../EU*.
  – The full text of the EU declaration of conformity is available at the following internet address

• Be continuously updated
• Translated into the language or languages required by the Member State in which the radio equipment is placed or made available on the market

Note: The single simplified DoC option would not be available where declarations against other directives are required
CE Marking (Article 19)

- General principles of Article 30 of Regulation 765/2008 apply:
  - affixed only by the manufacturer or his authorised representative.
  - affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product.
  - by affixing, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable Community legislation that require CE marking.
  - CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing.
  - Affixing markings, signs or inscriptions which are likely to mislead 3rd regarding the meaning or form of the CE marking are prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.
  - 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.
Rules and Conditions for CE Marking (Article 20)

- 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. It shall also be affixed visibly and legibly to the packaging.
- Affixed before the radio equipment is placed on the market.
- Followed by the identification number of the notified body where the conformity assessment procedure set out in Annex IV (FQA) is applied.
- Identification number of the notified body shall have the same height as the CE marking.
- Identification number of the notified body shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.
- Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.
• Not currently permitted but:
  – where radio equipment is fitted with an integral screen, the Commission should examine, as part of a review of the operation of this Directive, the feasibility of replacing the requirements for affixing:
    ▪ the manufacturer's name, registered trade name or registered trade mark
    ▪ a single point or postal address at which they can be contacted
    ▪ CE marking and DoC
  – with either a function whereby such information is automatically displayed upon starting up the radio equipment, or a function allowing the end-user to select the display of the relevant information.
  – As part of that examination of feasibility, where radio equipment fitted with an integral screen operates from an integral battery which does not hold an initial charge, the Commission should also consider the use of removable transparent integral screen covering labels which would display the same information.
Penalties for Infringements by Economic Operators (Article 46)

- Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.
- The penalties provided for shall be effective, proportionate and dissuasive.

Note: for products made available in several Member States, each Member State is entitled to enforce the RED using its own penalties.
Any questions?

Thank you for listening
Any questions?