



## **Nemko C355E**

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# **Provisions for certification – Electrical products – Radio Equipment Directive (RED) 2014/53/EU**

## PROVISIONS FOR CERTIFICATION OF PRODUCTS

### 1 ORIENTATION

Provisions for certification (Nemko C355E) regulates the Nemko activities associated with certification of products according to standards or other normative documents (hereafter called standards) for conformity marking of the products according to the Radio Equipment Directive 2014/53/EU. The certification system is independent of the interests of the parties and is based on type control (testing) and the manufacturer's internal control.

In addition to the standards for the product, which specify requirements and test methods, it is drawn up Special Provisions documents, which specify requirements concerning documentation which shall be submitted for certification. This document specifies requirements concerning the manufacturer's production control, requirements concerning type control and how the products shall be marked.

The prerequisite for gaining a certification license for conformity marking of products, is that the applicant undertakes to comply with the standard's requirements for the product and the Provisions for certification (Nemko C355E).

The latest editions of the documents shall always be used unless otherwise specified.

The following areas are covered for RED certification:

| Essential requirements                                                                          | Procedures | Articles/Annexes         | Categories of radio equipment | Comments |
|-------------------------------------------------------------------------------------------------|------------|--------------------------|-------------------------------|----------|
| Article 3.1.a                                                                                   | Module B   | Article 17 and Annex III |                               |          |
| Article 3.1.b                                                                                   | Module B   | Article 17 and Annex III |                               |          |
| Article 3.2                                                                                     | Module B   | Article 17 and Annex III |                               |          |
| Article 3.3.d                                                                                   | Module B   | Article 17 and Annex III |                               |          |
| Article 3.3.e                                                                                   | Module B   | Article 17 and Annex III |                               |          |
| Article 3.3.f                                                                                   | Module B   | Article 17 and Annex III |                               |          |
| Article 3.3.g NOT applied in conjunction with the Commission Decisions adopted under the R&TTED | Module B   | Article 17 and Annex III |                               |          |
| Article 3.3.g applied in conjunction with the Commission Decisions adopted under the R&TTED     | Module B   | Article 17 and Annex III |                               |          |
| Article 3.4                                                                                     | Module B   | Article 17 and Annex III |                               |          |

## **2 APPLICATIONS FOR CERTIFICATION LICENSES**

The application shall contain:

- For which aspects of the essential requirements the examination shall be performed
- Name and address for the manufacturer of the given product (if the applicant is an authorised representative, the name and address of this shall also be given)
- A declaration that no similar applications has been launched with any other Notified Body

Applications for certification licences or the extension of an existing licence shall be submitted using specific forms requested from Nemko.

Applications from dealers/importers shall be signed by both the applicant and the manufacturer of the product concerned. Dealers/importers have an obligation to keep the manufacturer oriented about the obligations and requirements that rest with the manufacturer with regards to conformity marking.

The requirements regarding the documentation that must be appended to an application are stipulated in the special provisions for the particular product.

The applicant, and the manufacturer if the applicant is not the manufacturer, undertake upon signing an application to comply with Nemko C355E for the products covered by the certification license.

### **2.1 Deadlines and appeals**

Nemko's certification under the Radio Equipment Directive is performed on behalf of Norwegian authorities by NKom, thus are bound by the "Public Administration Act" (Forvaltningsloven).

Deadlines for reply and casework are therefore bound by public administration rules.

- a) An application for certification shall be replied in writing to the applicant within 1 month.
- b) Nemko's decision shall be notified to the applicant in writing within 3 months.
- c) Appeal on a certification or rejection shall be notified to Nemko in writing within 3 weeks.
- d) The handling of appeals is performed according to the dealines as specified in a) and b).

### **3 CERTIFICATION LICENSE**

A certification license for a given product is issued when the report from type control confirms that all requirements of the relevant certification standard are fulfilled, see chapter 4.1, and the other documents enclosed with the application have been approved.

The certification license is specified according to the submitted documentation.

The right to use the compliance mark applies only to those products which have been listed in the certification license. The license owner is committed to comply with Nemko C355E for those products covered by the certification license. A license can only contain products from one manufacturer, but can contain products from different factory locations.

A certification license cannot be assigned to others.

The license owner is responsible for ensuring that the products covered by the certification license and which are marked, wholly meet the requirements in the certification standard, and that products are manufactured in accordance with the requirements of the standard. This means that in the event of any illegal marking of products that do not meet the requirements of the standards the license owner has an obligation to meet all the expenses associated with replacing the rejected products with products that comply with the standard requirements when so required.

The license owner shall in such cases also cover the expenses of the certification body.

#### **3.1 Validity**

A certification license is valid as long as the certification rules are fulfilled. If a certification license shall be cancelled, this must be submitted to the certification body in writing (letter template is available from Nemko).

A valid, signed edition of the certificate, shall always be available in original at the license owner. Void originals shall be deleted.

## **4 CONTROL**

By Control we mean testing and inspection, unless otherwise is specifically stated.

The Control includes:

- Type control performed upon request from the applicant, see chapter 4.1 below
- Control concerning changes to construction, materials, production, etc., see chapter 4.2 below

### **4.1 Type control**

Nemko issues certification licenses on the basis of passed type control. Type control shall be performed by Nemko. Sub-contractors shall not be used.

The type control shall be performed based on examination of the adequacy of the technical design of the product, by examination of the technical documentation.

Type control can be limited to certain parts of the essential requirements of the directive, according to the specification from the applicant/manufacturer.

The technical documentation shall enable the assessment of the product properties against the directive requirements, and shall contain relevant analysis and risk assessments. The documentation shall specify relevant requirements/standards and shall comprise design, production and operation of the product.

It is recommended to review the suggested checklist for risk analysis elements (can be requested from Nemko)

#### **4.1.1 Documentation**

Submitted documentation shall, as a minimum, contain:

- General descriptions of the product
- Undisputable definition of build status by HW/SW/FW versions and/or design documentation
- Detailed descriptions of all models to be covered by the certificate
- Conceptual drawings and schematics for design and production
- Circuit board drawings and layout drawings
- Component lists
- Technical specifications of the radio transmitter/receiver/transceiver
- Technical specifications of the antennas
- Copy of marking label(s)
- Assemblies and sub-assemblies
- Descriptions and explanations which supports the understanding of drawings and schematics
- Description of the operation and use of the product
- Does the product support operation without an active radio?
- Definition of the intended operating environment
- A list of the harmonised standards which has been applied either in full or partly
- If harmonised standards have not been applied, or just partly applied; a description of the solution applied in order to comply with the essential requirements of the directive, including a list of the relevant technical specifications which has been applied.
- If harmonised standards have only been partly applied; a description of which parts that has been applied
- Results and conclusions from design calculations, examinations, etc.
- Risk analysis
- Copy of EU Declaration of Conformity
- Test reports

#### **4.1.2 Type testing**

Type testing shall be performed according to the requirements of the relevant standard, and the type testing report shall confirm that the requirements have been met.

Test reports which are older than two years are normally not accepted.

When technical judgements are used as the basis for type testing in connection with the updating/-extension of licences, test reports that are older than two years old may, when it is considered appropriate from a technical testing viewpoint, be included. This assumes the testing methods comply with the relevant standards and the test results are representative vis-à-vis the product's relevant properties.

Non-accredited type tests must be qualified by the Notified Body by witness testing. If witness testing has not been used; Non-accredited type testing reports must be supported by additional documentation for instruments and testing equipment, test methods and personnel qualifications. More detailed information may be provided on request.

#### **4.2 Controls concerning changes to construction, materials, production, etc.**

In the event there is a desire to make changes to production factors (structure, materials, execution or production method) Nemko shall be informed and, on the basis of the information submitted regarding the change, adopt a position regarding the scope of the inspection the change will entail. Nemko shall approve the change in writing before the new production factor is implemented. Conformity marking may not commence before such written approval has been received.

In connection with considering a desire to change a production factor, there may be a need, at the applicant's expense, to gain an opinion from, or possibly perform a new type control.

The license owner may also seek permission for licences to cover changed products on the basis of opinions already obtained from approved bodies. This type of product may not be conformity marked before the revised edition of the certification licence has been issued.

## **5 USE OF CONFORMITY MARKS**

The owner of a certification license is entitled to mark those products covered by the license with the conformity mark which is specified in the given standard. Such marking shall be performed in a durable and clear way without damaging the product, in the manner and the location requested by the standard. If not specified, the conformity mark shall be located adjacent to other markings on the product.

The license owner is responsible for the performance of the marking, and that it is only applied to certified products. Marking is normally executed on the manufacturer's premises. If a dealer wishes to mark a product in accordance with a relevant standard, this may be done pursuant to a specific agreement with Nemko.

The right to apply conformity marks cease if the certification license is withdrawn by the certification body or is cancelled by the license owner. The right to apply conformity marks cease temporarily during suspension of the license.

## **6 FEES**

### **6.1 Control fees**

The costs for type control, internal control, external control and any other controls given in chapter 4, is paid by the applicant, respectively the license owner.

If the body finds it necessary, prepayment of control fees shall be accepted.

## **7 WITHDRAWALS AND SUSPENSIONS OF CERTIFICATION LICENCES**

Nemko may, with immediate effect, withdraw an issued certification licence if it is established that a license owner has utilised the conformity mark on or in connection with products that do not meet the requirements of a standard, or on products that are not covered by the certification licence. Furthermore, the licence may be withdrawn when a license owner has in some way or another violated the provisions on which the certification licence is based or if the instructions stipulated by Nemko in connection with its processing of a case are not complied with.

If the deviation is not of a significant character Nemko may suspend the certification licence until the circumstances are rectified within a stated deadline. Nemko is entitled to withdraw an issued certification licence if the annual fee and/or inspection fees are not paid within the permitted deadline.

If a holder of a certification license declares bankruptcy, enters liquidation or relinquishes its business, Nemko can similarly withdraw the certification licence with immediate effect. A holder of a certification licence who is notified that a licence has been withdrawn or suspended has an obligation to immediately cease all use of the conformity mark, sales of marked products and associated publicity or other advertising in which the conformity mark is included or mentioned in connection with the products concerned. If Nemko requires it, the licensee shall also remove the conformity mark from all products it deems relevant and which the manufacturer or a dealer has in storage, as well as from products that are already sold.

Misuse of the mark of conformity may entail liability and a duty of compensation both to the certification body and users of the certified product. The license owner has an obligation, in cases of a dispute, to allow these to be resolved in the legal jurisdiction of Oslo with Nemko as a party to the case.

Nemko is entitled to publish a decision regarding a suspension or withdrawal of a certification licence.

## **8 PUBLICATIONS**

Nemko maintains lists of holders of certification licences and of products for which certification licences have been issued. These lists are not public, but are available to national authorities.

## **9 REVISIONS OF THE RULES AND STANDARDS**

Nemko reserves the right to amend the Provisions for certification, Nemko C355E.

In order for a certification licence that has been issued in accordance with older rules to be able to be extended, a licensee has an obligation to comply with the revised rules.

If a standard upon which a certification licence is based is revised, it is a prerequisite for the extension of the licence that the licensee undertakes to comply with the requirements of the revised standard. The license owner shall however be given a reasonable amount of time to readjust to the requirements of the revised standard, if there are no specific reasons why this should not be so.

If a standard upon which a certification licence is based is replaced by a new standard a license owner must apply for a new certification licence. Guidelines regarding such an application will be provided by Nemko.

## **10 APPEALS/DISPUTES**

All disagreements that might arise in connection with these regulations shall be settled according to Nemko's appeal procedures.

## **11 REFERENCES**

**Directive 2014/53/EU** of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating the making available on the market of radio equipment.

[Directive \(EU\) 2022/2380](#) of the European Parliament and of the Council of 23 November 2022 amending Directive 2014/53/EU on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment

Guide to the Radio Equipment Directive 2014/53/EU Version of 19 December 2018.

**Decision No 768/2008/EC** of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products.

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