



Nemko C35XE

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Provisions for certification – Electrical and electronic equipment – EU RoHS Directive 2011/65/EU

Nemko Norway

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PROVISIONS FOR CERTIFICATION OF PRODUCTS

1 ORIENTATION

Provisions for certification (Nemko C35XE) 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 EU RoHS Directive 2011/65/EU and its amendments. The certification system is independent of the interests of the parties and is based on type control (testing) OR the manufacturer's internal control and Nemko's external 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 specify 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 C35XE).

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

2 APPLICATIONS FOR CERTIFICATION LICENSES

The application shall contain:

- Name and address for the manufacturer of the given product (if the applicant is an authorized representative, the name and address of this shall also be given)
- A declaration of Identical Materials when the application includes more than one model

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 C35XE for the products covered by the certification license.

2.1 Deadlines and appeals

Nemko's certification under the RoHS Directive is performed on behalf of Norwegian authorities by DSB, 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 deadlines 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 C35XE for those products covered by the certification license. A license can only contain products from one manufacturer and one factory location.

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

Nemko issues a certification license for 1 years. The certificate will contain the certificate 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
- Ongoing controls, see chapter 4.2 below
 - Internal controls, see 4.2.1
 - External controls, see 4.2.2

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/manufacture.

The technical documentation shall enable the examination 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
- BOM lists
- Internal and external photos of product
- A list of the standards which has been applied
- 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 one year are normally not accepted.

Type testing shall be performed in accredited test laboratory. Non-accredited type tests must be qualified by the Notified Body by witness testing and more detailed information may be provided on request.

4.2 Ongoing controls

Ongoing controls include internal controls, external controls and other controls as defined in this document.

Ongoing controls are performed in accordance with requirements of the standard. Nemko issues certification licenses on the basis of meet the requirements of the harmonized standard.

4.2.1 Internal control

Manufacturers who either themselves or through importers/vendors hold certification licences shall, on an ongoing basis, control and document that products which carry the conformity mark, meet the requirements of the standard, and that the products are manufactured in accordance with these requirements.

Internal controls shall, if not otherwise specified in the standard, be recorded in a journal which shall include all results, regardless of the outcome, and be kept for at least five years. Should the controlled products not meet the requirements, the license owner/manufacture has an obligation to immediately cease the marking of products with the conformity mark.

If the manufacturer has a certified ISO 9001 system, QC080000 system, the systems can be used, provided it meets the requirements for internal controls.

The license owner shall in addition record all complaints and corrective actions.

Non-conforming products shall be stored separately.

4.2.2 External controls

Once per year Nemko or a inspection body approved by Nemko will perform audit according to harmonized standard, including check technical file of product, the internal control at the manufacturer.

External controls shall be conducted as inspections of a manufacturer's internal inspections. Nemko therefore is not responsible for the manufactured products meeting the requirement in the standard or standards to which the licence refers. This responsibility is borne solely by the license owner.

4.2.3 Documentation

Submitted documentation shall, as a minimum, contain:

- General descriptions of the product
- BOM list of parts and/ or sub-assemblies and identification of which compliance criteria used.
- Manufacturers Quality procedure/documentation with process according to harmonized standard
- Exploded View of product/ detailed assembly drawings
- Device photos (internal and external)
- RoHS Test report for component
- Supplier's Declaration of Conformity for RoHS
- A list of the harmonized standards which has been applied
- Copy of EU Declaration of Conformity

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 C35XE.

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 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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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