RED Certification Rules

CERTIFICATION OF PRODUCTS UNDER THE IMPLEMENTATION OF THE DIRECTIVE RED 2014/53/UE

Edition n° 1

Changes compared to the previous edition:

- Introduction of Commission delegated regulation (EU) 2022/30 of 29 October 2021 (Cyber security)
- Editorial improvements

Document identification : RED_Règles Certification_ed.1

It has been approved by the BV-LCIE CEO on 22/04/2022

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SUMMARY

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1. Scope

The purpose of this document is to establish the certification rules that can be accredited by COFRAC according to ISO/IEC 17065, applicable to certification bodies operating for certification of products in the technical fields expressly covered by the Directive RED 2014/53/UE.

This accreditation is the basis for the appointment of the LCIE (Laboratoire Central des Industries Electriques) as Notified Body (hereinafter noted NB) according to RED Directive 2014/53/UE in accordance with the provisions defined by the French notifying authority (DGE-SQUALPI).

LCIE is involved in conformity assessment procedures of equipment, in order to issue on request of the manufacturer EU type examination defined in Annex III of the above mentioned directive.

The scope concerns the equipment as defined in Article 1 of the RED Directive 2014/53/EU

2. Reference documents

The certification of equipments is performed according to the following documents :

- RED Directive 2014/53/EU of the European Parliament and the Council of April 16, 2014 on the harmonization of the laws of Member States relating to radioelectric equipments.
- Commission delegated Regulation (EU) 2022/30 of 29 October 2021
- The list of harmonized standards published under Directive 2014/53/UE.
- The documents of the quality system for product certification, accredited accredited for the certification activities of industrial products and other non-agricultural and food products under number 5-0014, including mainly:
    - The Quality Manual “General Provisions” and the associated general procedures
    - The Quality Manual “Product Certification” and the specific procedures associated (meeting the requirements of the standards EN 45011 and ISO/IEC 17065)

3. Conformity Assessment

The RED Directive 2014/53/UE offers the choice between different conformity assessment procedures involving or not the Notified Body (NB):

1) conformity assessment procedure on the basis of an internal production control (Annex II of the Directive). In this case the Notified Body is not involved in the conduct of the proceedings (theses certification rules do not apply)

2) Conformity assessment procedure on the basis of an EU type examination, followed by Conformity to type based on internal production control. (Annex III of the Directive).

In this procedure, the notified body (ON) examine the technical file of the manufacturer to verify the compliance of the type of vis-à-vis device essential requirements requested.

The notified body shall establish an evaluation report outlining the activities conducted and their results.

Where the type meets the requested requirements, the notified body issue an EU-type examination certificate to the manufacturer. This certificate contains the name and address of the manufacturer, the conclusions of the review, aspects of the essential requirements covered

by the examination, conditions (if any) for its validity and the data necessary for identifying the approved type. One or more attachments can be attached to the EU-type examination certificate.

The EU type examination certificate and its annexes shall contain all information necessary to enable the conformiyy assessment of the equipment manufactured.

4. Conformity marking

The CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008, it is the manufacturer's responsibility.

The application of this compulsory labeling is not in the scope of application of this certification rules.

5. Related documents

Documents related to the certification rules are made available to applicants by LCIE

5.1 Application form:

Following the request, LCIE sends to the client the application form. This document is a commitment from the manufacturer of the intrinsic characteristics of the product to be certified according to the essential requirements of the Directive.

5.2 Technical documentation used in the procedure referred to Annexes III of the Directive

The applicant shall provide to LCIE a technical construction file including, where aplicable:

- ✓ a general description of the product, including
  - photographs or illustrations showing external features, marking and internal layout;
  - versions of software or firmware affecting compliance with essential requirements;
  - user information and installation instructions
- ✓ design and manufacturing drawings and layouts of components, sub-assemblies, circuits, ..
- ✓ descriptions and explanations necessary for the understanding of the drawings and schemes and the operation of the product,
- ✓ Adequate analisys and assessment of the risk;
- ✓ a list of the standards applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Directive where the standards have not been applied or do not exist,
- ✓ test reports

5.3 Documents issued by LCIE as Notified Body : Evaluation report and EU type examination certificate

The evaluation report traces the review activities by the notified body of the technical documentation and supporting evidence to assess the technical suitability of the equipment.

This EU type examination certificate is issued by the LCIE in case of satisfaction of the product with the essential requirements of the applicable Directive requested by the client. This certificate may be limited to certain aspects of the essential requirements according to the manufacturer's instructions or his agent under the requirements of Annex III of the Directive.

6. Obligations to be bound by the Applicant

The applicant is the legal person that may be the manufacturer or a designated representative.

Instead, third putting the product on the market under his name can be the applicant but must have an agreement with the manufacturer on compliance with the basic conditions to be observed during the production and control of the product.

The applicant undertakes to:

- maintain product compliance with the applicable requirements by supply arrangements, manufacturing;
- affix the CE marking and to appoint a representative within the Community as necessary;
- comply all the time without restriction or reservation with the provisions of this certification rules and the related documents, including changes that would be communicated by the LCIE;
- allow access to its premises and facilities, and ensuring access to the premises of the manufacturer of the product if the applicant and manufacturer are different, to the representatives of the Notified Body or his representative in connection with audits and controls products certified, and to any observers (eg mandated by COFRAC or a competent authority);
- Make presentations on certification that are consistent with the established certification and not misleading or not authorized by these certification
- Reproduce only in their entirety the documents issued by LCIE in the scope of certification (certificate, license, certificate type, ..).
- not submitted the same application to another notified body.
- pay all the fees relating to the certification of the products concerned;

Specific requirements when putting the product into circulation:

The manufacturer, its representatives, agents and importers of equipment are required to:

- ensure they place on the market equipment that comply with the essential requirements when installed and maintained properly and when they are used as intended,
- Comply with all requirements of the Directive 2014/53/UE, particularly in terms of reporting requirements and markings, as well as the requirement to the Notified Body.
- ensure that the user has good information on the use to which the equipment is intended,

- be able to identify the manufacturer or his representative in the European economic area if there is not domiciled, or the name of the importer and address on the product or packaging,
- take adapted measure to the particularities of the products they put into circulation in order to avoid danger. These measures may be the recall of equipment, effective and adequate warnings and the withdrawal of these products

In addition, the seller must verify that it sells only safe consumer products. It should therefore not putting on the market products whom they know or can think from the information available to it or experience they do not meet the basic requirements mentioned above.

7. Procedure for treatment of an application for Certification

7.1 General provisions and evaluation:

The applicant must complete the application form that is provided by LCIE and return it by enclosing construction technical file mentioned in Chapter 5.

The application relates to a product designated by the trade reference and its characteristics; may, however, be subject to a single application variants and accessories for a base model or more different products that can be assimilated to a family of identical nature products.

The applicant also specifies aspects of the essential requirements to be considered by the LCIE.

7.2 Assessment of the technical construction file:

The applicant provides to LCIE the technical documentation and, as applicable, a product sample if necessary for better analysis of the technical file.

LCIE examine the technical documentation and reports of type tests carried out to verify the product conformity with the essential requirements requested by the manufacturer and issues a construction dossier evaluation report.

7.3 Review and certification decision:

The review of the certification documents including the evaluation report allows a recommendation for certification decision, and to issue, when the decision is positive, EU examination type certificate, accompanied by any annexes and related reports if any.

7.4 Contesting a decision – Appeals

The applicant/holder may appeal a certification decision by sending the supporting material to the Certification Department of LCIE.

Appeals are heard by LCIE Certification Steering Committee. The applicant/holder shall be informed of the outcome of his appeal.

8. Survey of certified products

The equipment are subject to market surveillance carried out by the EU Member States under the provisions of Article 15, paragraph 3, and articles 16 to 29 of Regulation (EC) No 765/2008.

The applicant/holder of the EU-type examination certificate issued by LCIE is required to carry on manufacturing products certified regular monitoring in accordance with requirements of chapter 6 of these certification.

LCIE ensures through the provisions of this rules on the validity of EU type examination certificates issued.

9. Content of the EU type examination certificate

The basic information contained in the opinion are summarized in the table below:

Title	EU type Examination certificate
Notified Body details	*Notified Body Identification Number* The opinion also includes the logo and stamp of the Notified Body, as well as full details of the LCIE
Certification rules	Reference to RED certification rules
Certificate number	This unique number is mentioned on each page
Date of issuance of the certificate	Certificate issued on
Manufacturer details	Name Adress indicated in the first page
Scope of the certificate	Established according to article 17 (annexe III) of the 2014/53/UE directive
Equipment identification on the first page	Product Trade mark Model
Evaluation report identification	Evaluation report n° :
Conclusion	*LCIE declares that, the listed product complies with the essential requirements listed below:*
Signature	Name and function of signatory shall be indicated
Certificate validity	The EU type examination certificate has no validity sustainability concept and the following sentence is added: The validity of this certificate is limited to (x) product (s) subject of this type examination and the essential requirements examined. It must be reviewed in case of modification of the product (s) or in case of evolution of the state of the art
Accreditation	Reference to the issue of certificate under accreditation COFRAC, if applicable

LCIE follows the evolution of the status of the generally recognized technical; when this trend suggests that the approved type may no longer comply with the applicable requirements of this Directive, it determines whether additional tests are needed and prevents EU type examination certificate holder.

LCIE maintains a list of certified products including: the EU type examination certificate number, name and address of the holder, the reference type and model, and the product used for normative references conformity. This information can be provided on request.

LCIE also fulfills its reporting obligations as a body notified to the certification activities covered by this certification standard. These obligations are specified in Article 34 of Directive 2014/30 / EU.

10. Procedure in case of product change/withdrawal

Any modification of the certified product shall be subject to a written statement to LCIE. Depending on the nature and scope of the modification, and to conduct this review, the LCIE established a quote to the applicant.

Any final cessation of production of a certified product must be declared in writing to LCIE which shall withdraw certification.

In case of withdrawal of certification, the manufacturer cease any communication referring to the certification withdrawn.

11. Statement of Complaints

The applicant must:

- keep a record of any complaint brought to its attention about the conformity of a product with the requirements of the relevant standard and put the files in question available to the certification body upon request,
- take appropriate measures following such complaints or concerning any defects in a product that would affect its compliance with the certification requirements,
- document the steps that have been taken.

This statement must be made available if requested by LCIE.

12. Fees

The fees relating to the instruction of product certification According to the procedures described in §7 are the subject of an offer made pursuant to the rates in effect at LCIE.

The fees are payable to LCIE, by applicants in accordance with the rules specified in the offer. The provision of an order by the applicant constitutes acceptance of this offer.

13. Approval - Revision

These Certification Rules have been approved by the General Director of LCIE after consulting the Certification Management Committee and signature of the Director of Certification.

Any revision shall be submitted to identical process for approbation.