General Certification Rules



Scientific and Technical Centre of the Belgian Textile Industry

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Introduction

The European Directives and Regulations make it mandatory to affix the CE-mark or wheel mark on some products. By affixing the aforesaid marks, the manufacturer attests that the product is in conformity with the applicable legal safety and health requirements and that it is marketed in conformity with the legislation. The technical requirements with which the products have to comply are defined in the corresponding harmonized European standards or technical specifications.

Centexbel is a notified body # 0493 and is recognized to perform well-defined CE-type examinations and to carry out specific, periodical product verifications.

Subject

This set of rules specifies the general procedures, the method, responsibilities and rules CENTEXBEL, as notified body, applies in processing a certification application for products that fall under the scope of Centexbel (056-PROD) according to ISO 17065, see Belac website:

https://ng3.economie.fgov.be/NI/belac/Prodcert/scope_pdf/056-PROD.pdf

The product groups, for which Centexbel is accredited, are listed on the NANDO website:

http://ec.europa.eu/growth/tools-

databases/nando/index.cfm?fuseaction=notifiedbody.notifiedbody&refe_cd=EPOS%5F43815

For the specific certification rules per legislation, reference is made to § 6.4.

Reference documents

ISO 17065	Conformity assessment - Requirements for bodies certifying products, processes and services
ISO 17020	Conformity assessment - Requirements for the operation of various types of bodies performing inspection
ISO 17021	Conformity assessment - Requirements for bodies providing audit and certification of management systems
ISO 17025	General requirements for the competence of testing and calibration laboratories

Definitions

Applicant:

Legal entity applying for the certification of conformity of a product and engaging in maintaining this conformity. The legal entity is the manufacturer or his authorized representative in the European Union. Even if a third party (e.g. consultant) submits the application, the manufacturer remains responsible for the conformity of his product.

Notified body:

Accredited and independent institution that is authorized to carry out certain tasks (examination, monitoring and verification) in the framework of a European Directive/Regulation.

CE-marking:

Marking in a prescribed form, symbolizing that a product is in compliance with the essential safety and health requirements and promoting as such free trade within the European Union.

Certificate of constancy of performance:

Declaration by Notified Body that the product or product group is in compliance with the essential properties. Only applies to system 1.

Declaration of conformity:

Declaration drawn up by the manufacturer, who conforms that the article is in compliance with the applicable safety and health requirements. The contents of the declaration of conformity vary in function of the article and the system of conformity assessment that is applicable to it.

CPR:

Construction Products Regulation 305/2011

CWFT:

"Classified without further testing": products within the specified criteria that are automatically classified without testing.

EC Type-examination = Module B:

Assessment carried out by the notified body prior to the marketing of a PPE in the aim of establishing compliance with the applicable safety and health requirements. This assessment is based on the technical file of the manufacturer and on the models he provides.

EC type-approval certificate:

Declaration by the notified body that the product is in compliance with the essential safety and health requirements. Applicable to PPE of category 2 and 3.

EC quality control system for the final product (Module C2):

Conformity to type assessment carried out by the notified body based on internal production control and supervised product checks at random intervals to establish the constancy of conformity of the PPE with the applicable safety and health requirements by verifying the homogeneity of the production and the compliance with the technical file submitted during the type examination.

Expertise report:

Report by the notified body on the conclusions of the periodical product checks, carried out according to the systems defined in Module C2 or Module D of the PPER.

FPC:

Factory Production Control

FPC auditor:

A CENTEXBEL / CENTEXBEL SERVICES collaborator carrying out the FPC audit.

Harmonized standard:

European standard developed under the mandate of the European Commission, the reference of which has been published in the Offical Journal of the European Union. Harmonized standards give a presumption of conformity with the essential safety and health requirements, mentioned in annex ZA of this standard (for PPE and MED).

Initial FPC audit:

Initial verification carried out by the notified body within the company. It allows identifying and documenting the production process and serves as the basis of subsequent monitoring audits of the production process.

Withdrawal of the certificate: sanctions in the event of infringement:

Withdrawal of an existing type examination certificate after a first warning to a client (when on the occasion of the annual check it is observed that the claimed standards are no longer met).

MED:

Marine Equipment Directive 2014/90/EU

Follow-up FPC audit:

Verification carried out by a notified body within the company to guarantee the conformity with the technical provisions and to identify any modification regarding the initial FPC audit.

PPE:

Personal Protective Equipment

PPE:

Personal Protective Equipment Regulation (PPE) (EU) 2016/425.

Declaration of Performance (DoP):

Declaration drawn up by the manufacturer stating that the product or product group complies with the essential properties and that it applies to the attestation of all systems.

Product certifier:

A CENTEXBEL/Centexbel Services collaborator assessing the conformity of an article on the basis of a technical file.

Product family:

A group of products defined on the basis of production method and construction characteristics.

Production quality assurance (Module D):

Type conformity based on production process quality assurance. Periodical verification carried out by the notified body in the aim to establish the compliance of the product with the applicable safety and health requirements, by assessing the homogeneity of the production and the conformity with the technical file provided during the type examination.

Product verification (Module F):

Type conformity based on product verification

Product quality assurance (Module E):

Type conformity based on product quality assurance

Toys:

Products designed or intended, whether or not exclusively, for use in play by children under 14 years of age

Wheel mark:

Marking in a prescribed form, symbolizing that a product is in compliance with the essential safety and health requirements and promoting as such free trade within the European Union.

Systems to evaluate and verify performance consistency:

- System 1: Product or product group processed with flame retardant belonging to fire class $A1_{fl}$, $A2_{fl}$, B_{fl} or C_{fl}
- System 2: Not applicable
- System 3: Product or product group not covered by attesting system 1 or 4.
- System 4: Product or product group belong to fire class E_{fl} (within the CWFT-criteria) or F_{fl} (no performance determined), for which no fire report is needed.

Warning: sanctions at infringement:

First warning (in writing) to a client:

- when it is observed, during the annual check, that the claimed standards are no longer complied with
- 1 month prior to the expiring of a serious deficiency
- in the event of infringements reported by third parties

General requirements imposed to the certification institute

Legal and contractual matters

Prior to any certification order, an agreement is drafted between the applicant and Centexbel. The agreement refers to the general certification rules and to the specific certification rules.

Management of impartiality

CENTEXBEL has taken all necessary measures to guarantee impartiality in the decision to certification. This impartiality is monitored by the "Certification Council" that convenes at regular intervals. Manufacturers, users, authorities and experts are represented by the members of the "Certification Council".

Non-discrimination

CENTEXBEL opens its services to the applicants. Access to the certification process is not influenced by company size, membership or the number of already issued certificates. No illegal requirements are made to the applicant.

CENTEXBEL restricts the requirements, assessment, evaluation, decision and monitoring to those elements that are specifically related to the certification scope.

However, CENTEXBEL reserves the right to refuse the certification of a client in the event of fundamental and demonstrable reasons (e.g. illegal activities).

Confidentiality

CENTEXBEL shall treat all information related to the application as strictly confidential and not disclose it to third parties without the explicit consent of the applicant. This does not apply to that information that, in correspondence with the law, has to be provided to the supervising authorities or to other accredited verification instances.

Publically available information

The General certification rules and the specific certification rules are available to the public.

Anti-corruption directives

CENTEXBEL and CENTEXBEL Services performing tasks on behalf of CENTEXBEL shall carry their performances in an ethically correct manner. All legal regulations shall also be respected. Any form of bribery, fraud or corruption shall be notified to the quality manager, the head of department and the direction.

Financing

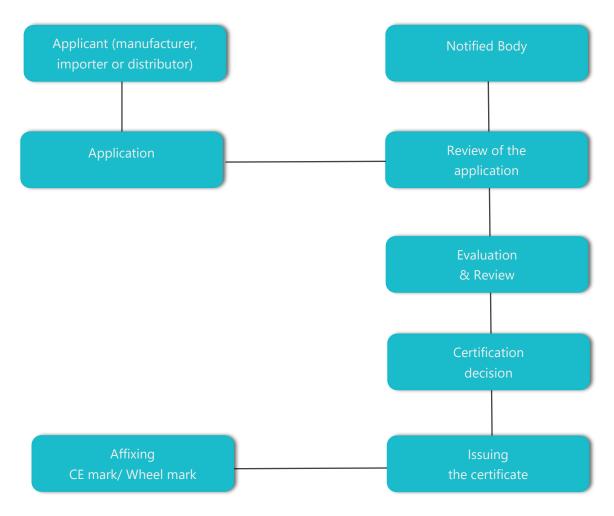
The fees charged by Centexbel for its services delivered, are determined in the 'Revenue Cycle memo' procedure (as to prices of the tests). For the certification activities (Type approvals - annual follow-up checks and inspections), the prices are saved on the server under the certification department. These are always available to customers on request. Certificates are delivered electronically only. If one wishes to obtain paper versions, a small extra cost is charged per delivered certificate. If you want a certificate in a language other than Dutch, French, English or German, extra certificate costs will be invoiced.

Certification process

The aim of the product certification is to verify and attest the conformity of an article with the applicable provisions of the Directive/Regulation during the design or production phase.

General FLOW certification procedure

Below, the certification process is described and if needed complemented in the specific certification rules.



Certification application

When a company wishes an article to be certified, it shall contact CENTEXBEL. The initial phase mainly includes the provision of general information on the course of the proceedings, including:

- definition of the product (group) based on production method and product characteristics.
- the required documents to be provided to CENTEXBEL.
- the signing of the mutual agreement setting out the rights and obligations of both parties with reference to these general certification rules and the specific certification rules.
- a quote drafted by CENTEXBEL for the work to be performed and discussion of the delivery date.

Review of the application for certification

CENTEXBEL/Centexbel Services evaluates the completeness of the information that the company provides in the <u>technical file</u> and, if needed, asks to provide <u>additional test samples</u> or <u>additional information</u> to complete the file. The applicant provides the necessary documents with identification and description of the defined products and product families and possibly also with materials. This first verification is only intended to verify the completeness of the file and shall in no way imply that the technical file or article is in conformity with the legal provisions. If the application is found inadmissible because of non-compliance with one of the above requirements, the applicant will be informed hereof.

Further proceedings of the certification process: evaluation and review

If the application is declared admissible, the file shall be evaluated by a qualified product certifier of CENTEXBEL/Centexbel Services who will contact the applicant to obtain documents, planning, etc. For the further proceedings of the certification process, we refer to the specific certification rules according to the applicable regulations. More in particular:

PPE: https://www.centexbel.be/en/certification/certification-rules

- CE-Type examination or Module B
- Periodical verification : Module C2 or Module D

CPR: https://www.centexbel.be/en/certification/certification-rules

- Initial type examination
- Initial FPC audit
- Follow-up FPC audit

MED: https://www.centexbel.be/en/certification/certification-rules

- CE-Type examination or Module B
- Production quality assurance (module D)
- Product quality assurance (module E)
- Product verification (module F)

TOYS: https://www.centexbel.be/en/certification/certification-rules

CE-Type examination or Module B

Certification decision

The decisions in view of certification are taken by the certification manager of CENTEXBEL who relies on the objective observations and reports of the qualified product certifier or the evaluating auditor and are weighed against the criteria of the certification rules, as well as against the possible reactions of the applicant. The certification decision is therefore substantiated by the results of the type examination or the follow-up check or FPC audit:

- in the event of a positive decision concerning the type examination, the certification manager of Centexbel signs the certificate that is then issued.
- in the event of a negative decision concerning the type examination, the certification manager of
 Centexbel informs the general manager and the applicant hereof. The refusal to issue the
 certificate shall also be notified to the supervising (notified) authorities and the other notified
 under this Regulation carrying out similar conformity assessment activities covering the same kinds of
 PPE.

Information to third parties

Centexbel will in certain cases, provide information to third parties as imposed by the regulations for which it is appointed.

For the Personal Protection Equipment Regulation

Any technical documentation and certifications may be accessed by the competent authority. On request of the competent authority or other notified bodies, Centexbel may provide a copy of the type-examination certificates and on a reasoned request also of a copy of the technical file, reports of the examination and tests.

Centexbel will inform competent authority of any certificates or quality system approval issued or extended and any refused, restricted, suspended or withdrawn certificate (Module B) or approval decision or restriction (Module C2, module F, module E or module D).

Centexbel will inform other notified bodies of any type-examination certificates and extensions or quality system approvals which it has refused, withdraw, suspended or otherwise restricted and will provide notified bodies carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues related to negative conformity assessment results.

In case of no appeal or in case the appeal is rejected, the refusal to issue the certificate shall be notified to the competent authority and the other notified bodies carrying out similar conformity assessment activities covering the same kinds of products.

For the Construction Product regulation

In case of any refusal, restriction, suspension or withdrawal of a certificate, Centexbel will inform the competent authority. Centexbel will also inform the other notified bodies of any negative result of an assessment or verification.

For the Marine Equipment Regulation

Centexbel will inform the competent authority of certification decisions. The competent authority and other notified bodies will also receive relevant information concerning EC type examination certificates and concerning quality-system approvals issued and withdrawn.

Obligations of the certificate holder

Each applicant shall be deemed to respect the general rules and provisions of the agreement between CENTEXBEL and the applicant, that has been concluded at the start of the certification procedure.

In addition, the certification holder shall be deemed to respect the applicable provisions of the European Directive/Regulation that is the subject of the certification. If the certificate holder appals to one or more harmonized standards or technical specifications, that give a presumption of conformity with the essential requirements of the articles, he shall also respect the provisions of these standards.

The certificate holder may only reproduce the certificate on which the accreditation symbol or reference to accreditation appears in its entirety. If this occurs only partially, it will have to bear the formal approval of CENTEXBEL.

When referring to accreditation by holders of a certificate issued by an accredited certification body, the conditions for referring to accreditation should be strictly followed, all necessary info can be found back at following:

https://economie.fgov.be/sites/default/files/Files/Publications/files/Belac-EN/BELAC-2-001-EN.pdf

Sanctions at infringement

When an infringement of shortcoming is observed, Centexbel reserves the right to take measures to sanction the certificate holder and to undo the infringement in proportion to the seriousness of the infringement.

In view of the monitoring of the certificates, two types of non-conformities may be specified:

- A minor non-conformity that is not compromising the quality of the product. The corrective action to such a shortcoming shall be verified during the following inspection. If the corrective action and its implementations are considered insufficient within the set period, the minor non-conformity becomes a major shortcoming.
- A major shortcoming is a non-conformity compromising the quality of the product. The certificate holder shall perform the corrective actions within the set period. If the corrective action and its implementation are considered insufficient within the set period, the corresponding certificate shall be suspended or withdrawn.

As long as non-rectified non-conformities are open, no certification or renewal of a certificate can take place.

If the client was unable to take appropriate measures to deal with the non-conformities, CENTEXBEL shall consider one of more of the following measures, depending on the urgency and/or importance of the non-conformity:

- **Observation**: if it is likely that a misunderstanding or negligence is at stake, the manufacturer shall at first be informed hereof in writing with the request to rectify and end the abuse. The latter shall reply to this in writing to allow the taken actions to be evaluated.
- A written warning: is sent as a standard one month prior to the expiring of a major shortcoming.
- Immediate withdrawal of the certificate or limitation of the application field: sent by registered mail
- Immediate suspension of a certificate during a well-defined period: sent by registered mail

In the event of presumption of malicious intent, Centexbel shall notify the certificate holder (if he belongs to the clientele of Centexbel) by registered mail of its findings by means of a warning and request to end the abuse as soon as possible. If this is not appropriately redressed in time, the supervising authorities shall be notified for advice on further steps, possibly by legal action. (It is also possible to proceed to the suspension or withdrawal of the certificate.) If the certificate holder is not a client of Centexbel, the authorised instance (FPS economy or FPS mobility) shall be notified.

Complaints and appeal procedure

Complaints

A complaint is any formal expression of dissatisfaction with Centexbel with regard to its certification activities, its clients or its services to clients. Any complaint against Centexbel must be made in writing and addressed to the Director-General. The Director-General of Centexbel will check the admissibility of the complaint. Centexbel will not treat anonymous complaints or expressions of dissatisfaction that are not substantiated as a complaint.

All complaints will be dealt with according to the Centexbel complaints management procedure. If the complaint is not submitted in writing, confirmation will be requested. Complaints will be confirmed and investigated in writing. The complainant will be informed of the outcome of the investigation. The complainant has the right to appeal if a complaint is not resolved to the satisfaction of the complainant.

Centexbel will determine, together with the complainant and the certified client, whether and to what extent the subject of the complaint and its resolution will be made public.

Appeal

The manufacturer or any other stakeholder may lodge an appeal against a certification decision made by CENTEXBEL. This shall be done in writing and be addressed to the general manager.

The general manager of Centexbel will evaluate the admissibility of the appeal. In order to be admissible, the appeal shall be a reasoned request and relate to a decision taken by CENTEXBEL. The admissibility will never relate to the validity of the reasons.

To avoid abuse, the appeal procedure is only started after the person lodging the appeal has paid a fee of 1,000 euros into Centexbel's account. Centexbel sends an invoice for this to the person lodging the appeal. The person who has lodged an appeal is informed that no action will be taken as long as the amount of 1,000 euros is not in Centexbel's account.

If the appeal is declared non-admissible, the general manager of Centexbel will inform the parties in writing of the reasons of the declaration of non-admissibility.

If the appeal is declared admissible, the general manager of Centexbel will summon an appeal board. This board will be composed of 2 persons appointed by the general manager who were not involved in the certification dossier against which the appeal was made. The person who appealed has the opportunity to explain and defend his/her case during the meeting of the appeal board.

The board will examine the case and decide to maintain or alter the decision. This will be communicated in writing to all parties involved. There is no possibility for further appeal against the decision of the appeal board.

Any appeal procedure against a certification decision shall be processed within four weeks.

Whatever the decision of the appeal board may be, the manufacturer cannot claim any compensation from CENTEXBEL for possible damages incurred.