Centexbel

Scientific and technical centre of the Belgian textile industry

General certification regulations

Personal Protective Equipment (PPE)

Contents

1 Introduction

The European Directive on Personal Protective Equipment decrees that CE-marking is mandatory for textile products intended to be used as Personal Protective Equipment. By means of this CE-marking the manufacturer attests that the product meets the relevant and fundamental legal safety and health regulations and that the product is placed on the market in conformity with the legislation. The technical requirements these products have to meet are defined in the corresponding harmonised European standards.

The Directive divides PPE into three categories, each subjected to a different conformity evaluation system:

- Category 1: the manufacturer drafts a technical file and affixes the CE-marking, without intervention of an external notified body
- Category 2: the manufacturer affixes the CE-marking after the notified body has performed a type examination on the basis of his technical file
- Category 3: after the type examination, a periodical inspection is carried out by a notified body. The manufacturer may choose the inspection system: product sampling or audit of the quality system. The manufacturer affixes the CE-marking, followed by the number of the notified body that carries out the inspections.

Centexbel is a notified body with number 0493 and is accredited for type examination and both systems of periodical inspections.

2 Object

This document specifies the procedures and regulations CENTEXBEL applies as a notified body in processing a certification application of products according to the Personal Protective Equipment Directive (89/868/EEC).

The product groups for which Centexbel is accredited are listed on the NANDO website: (http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=notification.pdf&dir_id=6&ntf_id=155901)

The products that are the object of this document belong to categories 2 and 3, as described in the 89/868/EEC Directive.

3 Definitions

PPE:

personal protective equipment

Applicant:

juridical entity applying for the certification of conformity of a product and engaging itself to maintain this conformity. This juridical entity is either the manufacturer or his authorised representative in the European Union. Even if the application is introduced by a third person (e.g. consultant) the manufacturer remains solely responsible for the conformity of his product.

CE-marking:

marking in a predefined form, symbolising that the product meets the essential safety and health requirement and thus promotes the free trade within the European Union.

PPED:

Personal Protective Equipment Directive (PPED) (89/686/EEC).

Harmonised standard:

European standard drafted under the mandate of the European Commission and which reference has been published in the Official Journal of the European Union. Harmonised standards indicate a presumption of conformity with the fundamental safety and health requirements, mentioned in annex ZA of this standard.

Notified body:

accredited independent institution authorised to perform a number of tasks (testing, type examination, periodical inspection) in the framework of the PPED.

EC Type examination:

examination performed by a notified body on a PPE that is put on the market and aimed at assessing the conformity with the fundamental safety and health requirements. This examination takes place on the basis of the technical file of the manufacturer and on the models he provides.

EC quality control system for the final product (art. 11A):

periodical inspection carried out by the notified body to ensure that the PPE continues to comply with the applicable safety and health requirements, by assessing the homogeneity of the production and the conformity with the technical file submitted at the time of the type examination.

EC quality control system for the production with supervision (art. 11B):

periodical inspection carried out by the notified body to ensure that the PPE continues to comply with the applicable safety and health requirements, by verifying the quality system of the manufacturer and the conformity with the technical file submitted at the time of the type examination.

Product certifier:

collaborator of CENTEXBEL assessing the conformity of a PPE on the basis of a technical file.

Declaration of conformity:

declaration drafted by the manufacturer confirming that the PPE complies with the applicable essential safety and health requirements. The content of the declaration of conformity varies according to the category to which the PPE belongs and to the corresponding system of conformity assessment.

Certificate of type examination:

declaration issued by the notified body that the PPE meets the applicable essential safety and health requirements. Applicable to PPE's belonging to category 2 and 3.

Inspection report:

report drafted by the notified body including the conclusions of the periodic inspection, carried out according to the systems described in 11A or 11B of the PPED.

4 General

The aim of the product certification is to assess the conformity of a PPE with the applicable regulations of the Personal Protective Equipments Directive (89/868/EEC) in the design phase or in the production phase and to attest this conformity.

5 Certification procedure

5.1 Certification application

When a company desires to certify a PPE it will contact CENTEXBEL. This initial phase primarily consists of providing general information on the procedure. It includes

- The definition of the product (or product group) on the basis of the production method and product characteristics.
- The required documents that have to be put at the disposal of CENTEXBEL.
- The signing of a mutual agreement laying down the rights and obligations of both parties.
- The drafting by CENTEXBEL of a price offer for the work to be performed and discussion of the delivery period.

5.2 Submission of the application and first verification

In this phase the applicant submits an application for certification to CENTEXBEL and declares to accept the price offer.

The product certifier of CENTEXBEL verifies whether the information that the company has provided in the technical file is complete and asks, if necessary, complementary specimen or additional information in order to complete the file. The applicant puts the necessary documents at the disposal with identification and description of the defined products and materials. This initial verification signifies by no means that the technical file or the PPE is in conformity with the legal regulations.

5.3 Type examination

After consultation with the applicant the *type examination* is performed. The technical file serves as a guide for this examination, based on the regulations of the PPED, more in particular annex II, and on the applicable harmonised standards or other technical specifications. During this examination, also prototypes are submitted to tests as foreseen in the corresponding harmonised standard or technical specification. These tests are carried out in the CENTEXBEL laboratories or by a subcontractor accredited in conformity with the requirements of ISO 17025.

The *product certifier* drafts a report including remarks and hands it to the applicant. The latter is required to carry out the necessary clarifications or corrections at his earliest convenience. Only when a positive response is given to all remarks, the product certifier submits a proposal to grant the certificate of type examination to the certification manager. If it is impossible to prove conformity, the product certifier will submit a proposal for refusal of the certificate of type examination to the certification manager.

5.4 Periodical inspections

Every year, following the initial type examination, Centexbel contacts the certification owner, in order to carry out a *periodical inspection* of the conformity of the PPE. The regulations of art. 11 of the PPED serve as a guide. The manufacturer may choose between the systems under art. 11A or 11B, but shall announce his choice during the type examination.

The *product certifier* carries out the inspection according to art. 11A at the manufacturer's site by taking representative samples and by having the necessary tests carried out on them.

The *product certifier* carries out the inspection according to art. 11B at the manufacturer's site by performing an audit of the latter's quality system, aimed at the conformity of the PPE that are the object of the verified certificates of type examination.

After both types of inspections, the product certifier drafts an inspection report including his observations. This report concludes whether the PPE is still in conformity with the legislation and corresponds with the model submitted at the time of the type examination and, if need be, which corrective measures have to be taken and by when. The proposed measures shall be in proportion with the impact of the deficiencies on the safety and health of the user.

The product certifier will submit his inspection report with the proposal for certification decision to the certification manager.

5.5 Certification decision

According to the results of the type examination or the inspection the certification managers takes one of the following decisions:

- In the event of a positive decision with respect to the type examination, the certification manager signs the certificate that he submits to the director general for signature.
- In the event of a negative decision with respect to the type examination the certification manager informs the director general and the applicant. The refusal to issue a certificate of type examination will, in conformity with the PPED, art. 10.6, also be communicated to the other notified bodies.
- In the event of a positive decision, possibly with remarks, with respect to a periodical inspection, the certification manager signs the inspection report. By this, the manufacturer has the right to affix the CE-marking to his PPE during one year (or during a shorter period if indicated as such in the inspection report).
- In the event of a negative decision with respect to a periodical inspection, the certification manager signs the inspection report and informs the director general and the certification owner hereof. The certificate of type examination will be withdrawn and, in conformity with the PPED, art. 10.6, the supervising authorities will be informed hereof.

6 Obligations of the manufacturer

Every applicant is supposed to respect the general regulations and stipulations included in the agreement that has been signed between CENTEXBEL and the manufacturer at the start of the certification procedure.

Furthermore, the manufacturer is supposed to respect the applicable regulations of the European Personal Protective Equipment Directive 89/868/EEC. If the manufacturer appeals to one or more harmonised standards, conferring a presumption of conformity with

the essential requirements of the PPED, he also has to respect the regulations of these standards, and more in particular those that are listed in annex ZA of the standards.

7 Sanctions in the event of infringement

If an infringement or deficiency is observed, CENTEXBEL reserves the right to take measures to sanction the manufacturer and to undo the infringement. The following measures are at the disposal and will be taken according to the gravity of the infringement:

- Warning
- Suspension of the certificate
- Withdrawal of the certificate

8 Appeal procedure

The manufacturer or any other interested party may appeal against a certification decision made by CENTEXBEL. This shall be done in writing and will be addressed to the director general.

The director general of CENTEXBEL will verify the susceptibility of the appeal. In order to be susceptible, the appeal shall be motivated and refer to the decision taken by Centexbel. The susceptibility concerns by no means the legitimacy of the motivation.

If the appeal is declared non-susceptible, the director general informs the involved parties in writing of the reasons for this declaration of non-susceptibility.

If the appeal is declared susceptible, the director general of Centexbel convenes an appeal committee. This committee is composed of 2 persons assigned by the director general who were not involved in the certification file against which an appeal has been made. The Appellant has the opportunity to clarify and defend his case during the meeting of the committee handling the appeal.

The committee examines the case and decides to maintain or to change the decision with respect to the certification. This will be communicated in writing to all parties involved. There is no further appeal against the decision of the appeal committee.

The treatment of an appeal against a decision with respect to certification has to take place within four weeks in any way.

Whatever the decision of the appeal procedure, the manufacturer cannot claim any indemnity from CENTEXBEL for possible damages.

9 Confidentiality

CENTEXBEL will treat all information with respect to the application as strictly confidential and will not disclose it to third parties without the express authorisation of the applicant. This does not apply to the information that, in conformity with the legislation, has to be communicated to the supervising authorities or to the other notified bodies.

10 Impartiality

CENTEXBEL has taken all necessary measures to guarantee the impartiality of the decisions in respect of certification. This impartiality is supervised by a “Certification Advisory Body” assembling in regular intervals. Manufacturers, users, authorities as well as experts are represented by the members of this “Certification Advisory Body”.