Specific certification rules for Personal Protective Equipment (PPE)

Scientific and technical centre of the Belgian textile industry

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1 Introduction

The regulation (EU) 2016/425 on personal protective equipment makes it mandatory to affix the CE marking on products used as Personal Protective Equipment (PPE). By means of this CE marking, the manufacturer* declares that the product complies with the essential safety and health requirements applying to PPE and that the product has been introduced on the market in conformity with the legislation. The technical requirements with which the products shall comply are described in the corresponding harmonized European standards or technical specifications.

* *Manufacturer: any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark.*

The Regulation distinguishes three PPE categories for which different conformity assessment systems apply:

1. *Category 1*: the manufacturer* drafts a technical file and affixes the CE marking, without intervention of an external notified body (auto-certification)
2. *Category 2*: the manufacturer* affixes the CE marking following the type examination performed by a notified body based on his technical file and issuing of the CE type examination certificate.
3. *Category 3*: after the type examination, an annual product check is performed by a notified body. The manufacturer* can choose the annual verification system to be followed: sampling or audit of the quality assurance system. The manufacturer* affixes the CE marking, followed by the identification number of the notified body that performs the annual verification.

Centexbel is a notified body number 0493 and is accredited to perform the type examination and both forms of annual product checks.

2 Definitions

See General Certification Rules

3 Certification procedure

3.1 CE Type examination or Module B

After consultation with the applicant, the *type examination* is performed. The technical file, based on the PPER requirements, and more in particular annex III, and the applicable harmonized standards or other technical specifications, serves as guidance for this examination. During the examinations, prototypes are also submitted to testing as specified in the corresponding harmonized standard or

technical specification. The tests are performed in the CENTEXBEL laboratories or at an accredited subcontractor in conformity with the requirements of ISO 17025.

The *product certifier* drafts a report including remarks and submits it to the applicant. The latter is demanded to make the necessary clarifications and/or corrections. Hereto, CENTEXBEL sets a maximum period of 6 months. If CENTEXBEL has not received the missing pieces within these 6 months, the file will be automatically put on hold and the reopening of the file after 6 months will result in a new certification cost (ISO 17065 §7.4). Only when a favourable answer is given to all remarks, the product certifier shall draft a proposal to issue the certificate of type examination and submit it to the certification manager. If it is impossible to demonstrate conformity, the product certifier shall submit a proposal for refusal of the certificate of type examination to the certification manager.

3.2 Periodical product checks

Every year, CENTEXBEL contacts the certification holder to perform a product check to monitor the conformity of the PPE. The requirements of Module C2/Module D of the PPER serve as guidance for this verification. The manufacturer* may choose between the systems under Module C2 or Module D, but shall communicate his choice at the EU-type examination.

The *Product certifier* performs a product check according to Module C2 by collecting samples at the manufacturer's* that are representative for the production and by submitting them to the necessary tests.

The *Product certifier* performs a product check according to Module D by performing an audit at the manufacturer's* site of the quality assurance system of the production process, oriented on the conformity of the PPE, that are subject of the verified certificates of type examination.

After having concluded both types of verification, the product certifier drafts an expertise report including a description of the verification results. This report states whether the PPE is still in conformity with the legal requirements and corresponds with the model that has been submitted for type examination and the possible corrective measures that have to be taken and their deadlines. The proposed measures shall be in proportion to the impact of the shortcomings on the safety and health of the consumer.

3.2.1 Quality assurance of the production process (module D)

After consultation with the applicant, the quality assurance of the production process or the FPC audit is performed. An FPC checklist serves as guideline for the audit. The focus of the audit is on the production of the product (product group).

The FPC auditor drafts an audit report that he hands over to the applicant and the product certifier. If no immediate corrective actions are required, the product certifier shall submit a proposal of decision for the product (product group) in question to the certification manager of CENTEXBEL.

If non-conformities are observed during the FPC audit, a time span, in relation to the nature of the non-conformity, will be communicated, during which the non-conformity shall be solved.

3.2.2 EU-quality assurance system of the final product (Module C2):

The product certifier performs a product check by collecting samples at the site of the manufacturer* that are representative for the production and by submitting them to testing. Afterwards, the product certifier drafts an expertise report, including the results of the product check. This report states whether the product (product group) is still in conformity with the legal requirements and corresponds with the model that has been submitted for type examination as well as any corrective measure and corresponding deadline. The proposed measures shall be in proportion to the impact of the shortcomings on the safety and health of the consumer.

The product certifier submits his expertise report with proposal for a certification decision to the certification manager of CENTEXBEL.