

Requirements for conformity assessments and Terms and Conditions for Certification

for conformity assessments according to Regulation (EU) 2016/425 on personal protective equipment

Disclaimer: This translation of form FL53092401 is for informational purpose only. The legally binding document detailing the Terms and Conditions for Certification is the German original „FL53092401 Zertifizierungsbedingungen PSA“.

1 Preliminary remarks

This document is structured as follows: sections 2 and 3: requirements to successfully complete a conformity assessment according to Regulation (EU) 2016/425 on personal protective equipment (PPE); section 4: Terms and Conditions for Certification, sections 5 and 6: legally binding information regarding information and complaints. By commissioning the Notified Body of the BEV (also if done through an authorized representative), the manufacturer takes note of these requirements, certification conditions and other information.

2 General requirements for conformity assessments

2.1 Application

The application must be submitted:

- by the manufacturer or
- by the manufacturer's authorized representative located in the European Union.

¹ The term „European Union“ denotes the member states of the European Union, the signatory states of the EEA and Switzerland.

In the case of an authorization, the following is required in addition:

- a written authorization by the manufacturer, issued to a natural person or legal entity, which clearly states the conferred tasks
- a possible previous authorization must be revoked at the same time
- a declaration by the authorized representative to bear all the costs of the conformity assessment procedure(s).

The authorized natural or legal person must assume the obligations stated in Regulation (EU) 2016/425 on personal protective equipment.

The application must contain:

- the name and address of the manufacturer and, if the application is submitted by the authorized representative, also their name and address
- the scope of the desired certification
- a written declaration that the same application has not been submitted to any other Notified Body
- the agreement to comply with the obligations imposed by Regulation (EU) 2016/425, the General Terms and Conditions (GTC's), as well as the Terms and Conditions of Certification stated in this document, and to provide all information required for this purpose
- the specific information listed in Section 3

2.2 Remuneration

The fees for the performance of the conformity assessment procedure set by the BEV in accordance with § 62 b, section 2 of the Measurement and Calibration Act (MEG) BGBl No. 152/1950, as amended, shall be paid by the applicant.

The expenses incurred by the technical testing of a product or by conducting audits will be charged separately by the Physico-Technical Testing Service (PTP) of the BEV. Quotes for these services can be requested from the PTP in advance.

2.3 Technical documents

The technical documentation must be submitted together with the application. The notified body of the BEV may request further copies of the documents if necessary. In accordance with Annex III of Regulation (EU) 2016/425, the technical documentation to be prepared by the manufacturer must contain:

- a) a complete description of the PPE and its intended use;
- b) an assessment of the risk(s) against which the PPE is intended to protect;
- c) a list of the essential health and safety requirements applicable to the PPE;
- d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
- e) the descriptions and explanations necessary to understand the drawings and schemes referred to in point (d) and the operation of the PPE;
- f) the references of the harmonized standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonized standards, the documentation shall specify the parts which have been applied;
- g) where harmonized standards have not been applied or have been only partially applied, descriptions of the other technical specifications which have been applied to meet the applicable essential health and safety requirements;
- h) the results of the design calculations, inspections and examinations performed to verify the conformity of the PPE with the applicable essential health and safety requirements;
- i) reports of the tests performed to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to determine the applicable protection class;
- j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE with the design specifications;
- k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
- l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
- m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

3 Specific information

The basic procedures for the modules, the required documents and the essential information and storage obligations are described in Annexes IV to VII of Regulation (EU) 2016/425. The requirements described below are based on this foundation.

3.1 EU type-examination (Module B)

3.1.1 Application

In addition to the information listed in Section 2.1 and the technical documentation listed in Section 2.3, sample(s) of the PPE representative for the planned production must be submitted together with the application. The notified body may request further samples if necessary for carrying out the testing program. For PPE produced in series where each item is adapted to fit an individual user, samples representative of the range of different users shall be provided. For PPE produced as a single unit to fit an individual user, a basic model shall be supplied.

3.1.2 Maintaining the certification

The Notified Body of the BEV will keep a copy of the documents on which the certification is based. The Notified Body must be informed of any changes to the content of these documents and/or to the product itself that affect conformity. If necessary, a review procedure will be initiated. In case of a desired extension, the manufacturer shall submit an application for review at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate.

If the Notified Body gains knowledge of deficiencies in products placed on the market, the manufacturer will be notified, and corrective action with an appropriate time limit will be requested. In case of systematic non-compliance with the requirements of Regulation (EU) 2016/425 despite a request by the Notified Body to restore the proper condition, the Notified Body may revoke type examination certificates. The revocation of type examination certificates issued by the Notified Body of the BEV shall be published on the homepage of the BEV and notified to other Notified Bodies and, if necessary, to authorities.

The type examination certificates issued by the Notified Body of the BEV and their amendments are published on the homepage of the BEV.

3.2 Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)

3.2.1 Application

In addition to the information listed in Section 2.1 and the technical documentation listed in Section 2.3, the application shall include the following documentation:

- a) identification of the PPE concerned/the scope of certification requested
- b) a copy of the EU type-examination certificate (if the notified body selected is not the notified body which carried out the EU type-examination)

- c) Declaration concerning the measures taken to ensure that the manufacturing process and its monitoring guarantee the uniformity of manufacture and the conformity of the PPE to the type described in the EU type-examination certificate and with the applicable requirements of Regulation (EU) 2016/425.
- d) Possibly samples of forms and of the declaration of conformity (not mandatory)

3.2.2 Procedure

The essentials of the procedure are:

1. application for conformity assessment according to module C2 and submission of the documentation by the manufacturer or the authorized representative (hereinafter simplified as "manufacturer").
2. examination of documents, if necessary additional request of missing documents
3. after positive evaluation of documents: planning and execution of first sampling (no later than one year after the date of issue of the type-examination certificate) and product tests.
4. after positive evaluation of first product tests: signing of the surveillance contract for the annual sampling and product tests
5. issuance of certificate authorizing manufacturer to affix the identification number of the NB BEV onto products complying with Regulation (EU) 2016/425 and with the type examination certificate
6. annual sampling (at irregular intervals) and product testing to determine whether the uniformity of manufacture is ensured and the products comply with the essential health and safety requirements.

3.2.3 Maintaining the certification

The validity of the certification is linked to the validity of the type-examination certificate. The Notified Body of the BEV keeps a list of the documents on which the certification is based. The Notified Body must be informed of any changes to the content of these documents and/or to the product itself that affect conformity of the products, the scope of certification or its basic conditions. If necessary, a revision procedure will be initiated. If the Notified Body gains knowledge of deficiencies in measuring instruments placed on the market, the manufacturer will be notified, and corrective action with an appropriate time limit will be requested. In case of systematic non-compliance with the requirements of Regulation (EU) 2016/425 despite a request by the Notified Body to restore the proper condition, the Notified Body may the certificate.

3.3 Recognition of the QM system (Modul D)

At present, Module D is not included in the scope of accreditation of the product certification body and the scope of notification

3.3.1 Application

In addition to the information listed in Section 2.1, the application shall include:

- a) the address of the manufacturer's premises where the audits may be conducted;
- b) the identification of the PPE concerned;
- c) the documentation of the quality system.

If the selected body is not the body that performed the EU type examination, the application shall also contain the following:

- d) the technical documentation of the PPE listed in section 2.3, in accordance with Annex III;
- e) a copy of the EU type-examination certificate.

3.3.2 Documentation of the quality system

The quality system shall ensure conformity of the products with the types described in the EU type-examination certificates and with the applicable requirements of the Regulation on personal protective equipment. This must be documented in the quality system in the form of written policies, procedures and instructions.

According to Annex VIII Module D, Regulation (EU) 2016/425 on personal protective equipment, the documentation of the QM system must contain an adequate description of the following points:

- Quality objectives and organizational structure, responsibilities and powers of the management with regard to product quality;
- The corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned, and
- the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

Documentation typically includes (but is not necessarily limited to):

- Quality management manual
- Organizational charts

- Personnel listing including responsibilities
- Proof of competence of the employees working in this area
- Procedural and work instructions
- Description of the means used to monitor product quality
- List of measuring equipment used
- Copies of the EU type-examination certificates
- Sample of the declaration of conformity
- If applicable, proof of certification according to ISO/IEC 9001

3.3.3 Assessment of the quality assurance system: procedure

The key points of this procedure are as follows:

1. Application for assessment of the quality system and submission of the documentation by the manufacturer or the authorized representative (hereinafter simplified as "manufacturer").
2. After examination of the application, the Notified Body sends the draft surveillance agreement and information about the audit team to the manufacturer. The audit team is selected to ensure an impartial procedure. The manufacturer has the possibility to object to the appointment of the auditors.
3. Examination of documents, if necessary additional request of missing documents by the audit team
4. Stage 1 audit: obtaining sufficient knowledge and scope of the management system to plan the focus of the main audit (stage 2). Important topics: Mapping of the specific requirements of the Regulation (EU) 2016/425, the harmonized standards or normative documents, and, if applicable, specifications in the EU type examination certificates in the management system and its processes. If necessary, in case of a new introduction of the management system (i.e. certification according to ISO/IEC 9001 is not available), the progress in the introduction as well as the preparation on the part of the personnel is assessed for scheduling the main audit. The result of the stage 1 audit is documented in writing and communicated to the manufacturer. It identifies the areas that still give rise to reservations and that could be identified as a nonconformity in the main audit.
5. Incorporation of the findings of the stage 1 audit by the manufacturer
6. Audit plan is sent to the manufacturer, stage 2 audit is scheduled
7. Stage 2 audit: The effectiveness of the quality assurance system is checked, in particular with regard to the conformity of the products with all requirements of the Regulation (EU) 2016/425, the applicable harmonized standards, normative documents and, if applicable, specifications in the EU type examination certificates. The main audit is documented in the audit report.
8. Corrective action on any findings on the part of the manufacturer and verification of the corrective action by the audit team

9. Certificate on the approved quality system is issued, authorization to affix the notified body's identification number to the conforming products.

The certificate of the approved quality system is valid for a period of 3 years from the date of the approval decision. The Notified Body of the BEV keeps a list of the documents on which the certification is based. The Notified Body must be notified of any changes in the content of these documents and in the quality assurance system itself that affect the conformity of the PPE, the scope of certification or its basic conditions. If necessary, a revision procedure will be initiated.

3.3.4 Maintaining the certificate

The Notified Body shall perform one announced audit per year, and, before the expiry of the certificate after three years, a re-certification audit assure itself that the quality system is maintained and applied by the manufacturer. The first surveillance is carried out within 12 months after issuance of the first certificate. Furthermore, inspections can also be carried out without prior notification. During these inspections, full or partial audits can be carried out. The manufacturer receives an inspection report and, if applicable, an audit report.

If the Notified Body gains knowledge of deficiencies in products placed on the market, the manufacturer will be notified and corrective action with an appropriate time limit will be requested.

The recognition shall be suspended if:

- the quality system persistently or seriously fails to meet the certification requirements (e.g. serious/numerous deficiencies in the documentation or products, doubts about the competence of the personnel);
- the manufacturer does not allow the audits to be carried out,
- the manufacturer has voluntarily requested a suspension.

Verification of the elimination of the deficiencies that led to the suspension is carried out by means of a document review or an audit. If the deficiencies occur repeatedly or if the deficiencies that led to the suspension are not corrected within the specified period, the recognition is restricted or withdrawn.

4 Terms and Conditions for Certification

The manufacturer ensures that:

- declarations of certification are made only with regards to the products or activities for which certification has been granted;
- the certification is not applied in a way that discredits the Notified Body of the BEV;

- no statements are made about the certification that the Notified Body may consider misleading and unauthorized;
- after suspension or withdrawal of certification (caused by whatever means), all advertising referring to certification in any way is discontinued and all certification documents requested by the Notified Body of the BEV are returned;
- no certification document, certification mark or certification report is used, in full or in part, in a misleading manner;
- copies of the certification documents are reproduced and given to third parties only in their entirety;
- the requirements of the Notified Body of the BEV are met whenever reference is made to the certification in communication media, such as documents, brochures or advertising material.
- records are kept of all complaints regarding the conformity of a product and these records are available to the Notified Body of the BEV upon request;
- appropriate action is taken and documented with respect to such complaints and regarding any defects found in products that affect conformity and compliance with the certification requirements;
- the Notified Body of the BEV is informed of any relevant changes (e.g. intended modification of the product, the manufacturing process, or the quality assurance system) that may affect product conformity. The Notified Body shall determine whether the announced changes require further investigation. Certified products resulting from such changes shall not be released until notified by the Notified Body of the BEV.

Any use of BEV symbols, marks or logos is subject to prior written approval by the BEV.

Reference to the certification and the use of signs is possible:

- a) in correspondence (within the scope of the certification)
- b) in publications (not on business cards).

Any reproduction which is detached from a correct reproduction of the NB BEV documents relating to the certification shall not be permitted. Any partial reproduction of the certification documents for the purpose of passing them on to third parties is not permitted.

The accreditation mark, which is depicted in the certificates of the NB BEV on page 1, must not be misused. Any use is contingent upon written permission.

The use of the accreditation mark on products that have been assessed for conformity is prohibited. The users of accredited services are not permitted to use any combined logos containing the ILAC MRA mark or the ILAC MLA mark.

5 Treatment of information

The management and the employees of the Notified Body are legally bound to official secrecy with regard to all information of which they have become aware in the course of carrying out their tasks under the EU Directives.

Upon official request of a member state, the Notified Body of the BEV is obliged to produce the documents on which the recognition is based. Aside from this case, information obtained from the conformity assessment procedures will only be disclosed to third parties with the prior consent of the manufacturer.

Certificates as well as related amendments (revisions) are published in the „Amtsblatt für das Eichwesen“ and on the website of the BEV (www.bev.gv.at). Technical annexes are excluded from this publication. All other information from conformity assessment procedures is treated confidentially and protected against unauthorized access. If legal obligations require that further information is made publicly available by the Notified Body, the manufacturer will be informed in writing.

The manufacturer will be informed in writing by the Notified Body of the BEV about changes in the requirements.

6 Handling of complaints

Complaints as intended in the standard EN/ISO 17065 are processed in accordance with the stipulations of the Quality Management Manual of the Notified Body of the BEV. The receipt of a complaint is confirmed by the Notified Body; the manufacturer is informed about the further handling and the conclusion of the complaint procedure.