Bundesamt
für Eich- und
Vermessungswesen
Notifizierte Stelle NB 0445

SNAS
Reg. No. 737/P-054

bev.gv.at

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Leaflet for a certification according to Regulation (EU) 2016/425 on personal protective equipment (PPE)

Content

1. General provisions

1.1. Application on certification

The application shall be submitted

- By the manufacturer himself or
- By the authorized representative established in the Member States[1].

If the physical-technical inspection or assessment - which is not a sovereign task - is to be carried out by the physical-technico testing service (PTP) of BEV, the BEV PTP must be expressly commissioned to do so in the application.

In the case of an authorization is additionally required:

- Authorization of the manufacturer, who grants it to a company (or person) established in the Member States
- Declaration by the authorized applicant to bear all costs of the conformity assessment procedure(s) incl. invoice of physico technical service of the BEV.

The authorized company (person) has to assume the obligations lay down therein as applicant according to Regulation EU 2016/425 on personal protective equipment. If a company rather than a person is authorized, the company must name a physical person as the authorized recipient.

In any case, the application includes:

- Information about the manufacturer
- The scope of the desired certification
- The information referred to in points 2.1.1, 2.2.1 and 2.3.1
- Agreeing to comply with the certification requirements and providing the necessary information

1.2. Fees

The fees mentioned are to be paid according to the Fees and Duty Act 1957, Federal gazette no. 267/1957 as amended and the ordinance on verification fees 1999, Federal gazette no. II 467/1998 amended through ordinance Federal gazette no. II 311/2013.

Application and authorization (§ 14 of the Fees and Duty Act): 14.30 € each.

Enclosures (§§ 5, 14 of Fees and Duty Act): 3.90 € per sheet, maximum 21.80 € per enclosure.

The further procedural costs depend on the effort involved and can be clarified in the event of an incident. The expenses incurred in testing the PPE are charged separately by the Physical-Technical Testing Service.

1.3. Enclosures

Depending on the scope of certification, all relevant documents are to be enclosed to the application. The BEV may ask for further documentation if necessary (without any fees).

[1] In the following, member states are defined as the member states of the European Union, the contracting states of the EEA and Switzerland.

The inserts must meet the following requirements according to the EU Regulation 2016/425 on personal protective equipment (PPE). The technical documents to be prepared by the manufacturer must contain the following information according to Annex III of Regulation EU 2016/425:

a) A complete description of the PPE and of its intended use;
b) An assessment of the risks against which the PPE is intended to protect;
c) A list of the essential health and safety requirements that are 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 for the understanding of the drawings and schemes referred to in point (d) and of 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) If there are no harmonized standards or only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
h) The results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
i) Reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant 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 produced 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.

2. Module-depending requirements

2.1. Module B – EU Type-examination

2.1.1. Application

According to Annex V Module B, Regulation EU 2016/425 on personal protective equipment, the application must contain the following:

a) The name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well;
b) A written declaration that the same application has not been lodged with any other notified body;
c) The technical documentation described in Annex III;
d) The specimen(s) of the PPE representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test program. For PPE produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, and for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.

2.1.2. The Documentation

Required is the documentation according to Annex III of Regulation EU 2016/425, which is listed in point 1.3.

2.1.3. Changes to the type

Changes to the type samples shall be notified to the notified body and an application for verification shall be made. The review of the EU type examination certificate in case of a desired extension has to be applied for at the earliest 12 months and at the latest 6 months before its validity expires.

The type examination certificates issued by the Notified Body of BEV and their changes will be published on the BEV homepage.

2.2. Module C2 - Conformity to type based on internal production control plus supervised product checks at random intervals

2.2.1. Application

According to Annex VII module C2, Regulation EU 2016/425 on personal protective equipment, the application must contain the following:

a) The name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address;
b) A written declaration that the same application has not been lodged with any other notified body;
c) The identification of the PPE concerned.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

a) The technical documentation described in Annex III;
b) A copy of the EU type-examination certificate the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address;

2.2.2. Documentation

- The documentation is to be provided essentially in the form of declaration concerning the measures taken to ensure that the manufacturing process and its monitoring ensure the uniformity of manufacture and the conformity of the PPE manufactured with the type described in the EC type-examination certificate and with the applicable requirements of this Regulation.
- A copy of the EU type-examination certificates (if selected body has not carried out the EU type-examination)
- Technical documentation according to Annex III of Regulation EU 2016/425 (if the selected notified body has not carried out the EU type examination)
- Possibly sample forms and sample declaration of conformity (not mandatory)
- Scope of certification applied for
- PPE list (identification of the protective equipment concerned)

2.2.3. Procedure

1. The procedure is basically performed as follows: 1. application for recognition and transmission of the documents
2. Examination of the application
3. Notification of the surveillance agreement
4. Assignment of a auditor
5. Carrying out the necessary tests
6. Annual product tests are carried out at irregular intervals.

The assessors are selected in such a way that an impartial procedure is ensured. You have the opportunity to object to the appointment of the officers during on-site monitoring.

Information from the procedure is treated confidentially and protected against unauthorized access. Such information will only be disclosed with your prior consent. You will be notified of any information that we publish.

2.2.4. Maintenance and extension of the agreement

The Notified Body shall carry out product tests at irregular intervals on an annual basis. Changes to the type samples or possible extensions of the products for which the conformity assessment is carried out shall be notified to the notified body.

2.3. Module D – Conformity to type based on quality assurance of the production process (!!! Not currently in the scope of accreditation of the product certification body / scope of notification)

(!!! At the moment, module D is not yet included in the scope of accreditation of the product certification body / scope of notification. For more information on this, please contact Notifizierte-Stelle.PSA@bev.gv.at)

2.3.1. Application

a) According to Annex VIII Module D, Regulation EU 2016/425 on personal protective equipment, the application must contain the following:(a) the name and address of the manufacturer and, if the application is lodged by the representative, his name and address as well;
b) the address of the manufacturer's premises where the audits can be carried out;
c) A written declaration that the same application has not been lodged with any other notified body;
d) The identification of the PPE concerned;
e) The documentation concerning the quality system.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

a) The technical documentation of the PPE described in Annex III;
b) A copy of the EU type-examination certificate.

2.3.2. Documentation

The documentation is to be provided essentially in the form of:

- Quality Management Manual
- Procedure and work instructions
- Documentation on the quality assurance system
- Supplementary information on which parts of the documentation cover which standard points (check list for laboratories according to EN ISO 9001:2015)
- Evidence of tests carried out before, during and after manufacture, and the frequency with which they were carried out
- Test reports, test and calibration data as well as the proof of competence of the employees working in this area
- Details of the means of monitoring product quality
- One copy of the EU type examination certificates (if selected body has not carried out the EU type examination)
- Technical documentation according to Annex III of Regulation EU 2016/425 (if the selected notified body has not carried out the EU type examination)
- Specimen forms and specimen declaration of conformity
- Scope of certification applied for
- List of personnel
- PPE list (identification of the protective equipment concerned)
- List of documents

2.3.3. The documentation of the Quality System

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

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

2.3.4. Recognition procedure

The approval procedure is basically performed as follows:

1. Application on approval of the QM-System and transmission of the documents
2. Examination of the application
3. Transmission of the surveillance agreement and information about the audit team
4. Assignment of the audit team (usually two experts covering the organization of the audit, the QM, the working field and the implementation of the directive)
5. If necessary, additional documents will be requested by the experts
6. Examination of the documents
7. Sending of an audit plan
8. Document review
    - Provision of sufficient information about the company and its management system for the planning of the extent and the focus of the audit of stage 2.
    - What is the extent of the management system? Which processes and locations are covered by this system? Are there statutory and regulatory aspects? How are they complied with?
    - Do the business processes at the different locations and the site-specific conditions meet the standard requirements?
    - Do the condition of the enterprise and the understanding of the standard requirements meet the expectations, especially as far as the identification of important activities, processes and objectives as well as the operation of the management system is concerned?
    - Is the documentation of the management system in good order?
    - Do the planning and execution of the internal audits and the management review meet the standard requirements? Is the introduction of the management system advanced sufficiently enough in order to execute the main audit of stage 2?
    - Are the personnel ready for the execution of the main audit (stage 2) and are the necessary resources available?

    The result of the document review audit is documented in writing and communicated to the applicant. Non-conformities will be communicated to the applicant with a deadline for correction.
9. Audit/assessment
    The audit is carried out according to an audit plan agreed in writing with the applicant.

The audit serves to check whether the management system has been introduced and whether the intended effect is achieved. It is carried out at the applicant's site and covers at least the following aspects:

- Information and evidence about conformity to all requirements of the applicable management system standard or other normative document;
- Monitoring of the performance, i.e. measurement, report and assessment with regard to the most important performance goals (in agreement with the applicable standard requirements or other normative document);
- The client's management system and performance as regards legal compliance;
- Operational control of the processes;
- Internal auditing and management review;
- Management responsibility for the client's policies;
- Evidence of accordance between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

The main audit is documented by an audit report.

10. The approval is valid for a period of 3 years beginning with the decision of the approval. Annual supervising audits take place.

The auditors are chosen in such a way, that an impartial approval procedure is ensured. You have the possibility to disagree on the nomination of auditors.

Information from the approval procedure is kept confidentially and protected against unauthorized access. Such information is communicated only after prior consent by you. You will be informed about any information published by us.

2.3.5. Maintaining and extending recognition

The Notified Body carries out an announced audit each year and a re-approval audit before the expiration of the approval in order to ascertain that the manufacturer updates and applies the quality assurance system and prepares an audit report which is provided to the manufacturer and kept ready for the Federal Ministry for Digital and Economic Affairs (BMDW). The first audit has to take place within 12 months after the approval.

Furthermore, monitoring can also be carried out without prior notice in the form of full or partial audits. The manufacturing company receives a report.

In the case of minor defects, a deadline is set for rectification. In the case of serious and/or numerous deficiencies in the documentation, doubts about the competence of the personnel, as well as deficiencies in the manufactured PPE, recognition is suspended until the deficiencies have been rectified.

The approval is suspended if:

- The quality management of the manufacturer does not meet the approval requirements persistently or gravely;
- The manufacturer does not permit the execution of the surveillance or reapproval audit;
- The manufacturer asked for a temporary suspension voluntarily.

The withholding of the approval is carried out by notice with dead-line; the related requirements are communicated in the conditions.

The examination of the correction of the non-conformity which led to the suspension is carried out by control of the documents or audit, respectively.

If the deficiencies mentioned above arise repeatedly or the non-conformities which led to a suspension are not corrected within the dead-line given, the approval will be limited or withdrawn.

If you apply for the extension of the scope of the recognized QM system a new audit is necessary in order to be able to decide if this extension can be granted.

3. Obligations due to approval

The applicant assures:

- That all necessary arrangements for the conduct of the assessment, including provision for examining documentation and the access to all areas, locations, records (including internal audit reports), client`s subcontractors and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints are provided;
- E.g. observers can take part on the audits and surveillance;
- Claiming of certification with respect to those activities only for which it has been certified;
- That its certification is not used in such a manner as to bring the NB into disrepute, and that there is no statement regarding its certification which the NB may consider misleading or unauthorized;
- That upon suspension or withdrawal of its certification (however determined), use of all
- Advertising matter that contains any reference thereto will be discontinued and any certification documents will be returned as required by the NB;
- That certification is only used to indicate that the quality system is in conformity with specified standards or other normative documents, and does not use its certification to imply that a product or service is approved by the NB;
- That no certification document, mark or report, or any part thereof, is used in a misleading manner;
- Copies of certification documents are only valid as a whole to be distributed to third parties
- That making reference to its certification in communication media such as documents, brochures or advertising, complies with the requirements of the NB.
- Corrective actions are taken whenever the conformity of products is injured.
- That the records of all complaints and corrective actions taken in accordance with the requirements of the quality system standards or other normative documents are available for the NB.
- That the NB is informed about all relevant changes, e.g. modification of products, procedures, quality management system, which may lead to influence on product conformity. The NB will decide whether further investigations are necessary. Modified products may be brought on the market after release by the NB.

4. Confidentiality

The certification body is responsible, through legally commitments, to treat all information obtained or created during the performance of certification activities in the framework of EU directives, as confidential.

The information from certification procedures are given to third parties only after prior consent of the applicant(s). Applicants are also informed in writing about the information which the NB has to give by obligation to law to the public.

5. Dealing with objections and complaints

Objections in the conformity assessment procedure are dealt with according to the “Allgemeines Verwaltungsverfahrensgesetz” (General administration procedure act, AVG). Suggestions to improve the services of the BEV notified body for PPE can be made at any time. The receipt of the objection is confirmed in writing.

6. Withdrawal of EU type-examination certificates

If, despite the Notified Body's request, the proper condition of the products concerned is not produced in due time in case of systematic non-compliance with the requirements of Regulation EU 2016/425 on personal protective equipment, the Notified Body may revoke the type examination certificates. The revocation of the type examination certificates issued by the Notified Body of BEV for PPE will be published on the homepage of BEV

7. Notes

Certificates and changes concerning the certificates are published in the Official Bulletin of the Metrology Service and on the Website www.bev.gv.at (in detail on http://www.metrologie.at/).

The documents forming the base of the approval have to be provided to the member state by the Notified body PPE of BEV on request.

You will be informed in writing about changes of requirements by the Notified Body PPE of BEV.