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für Eich- und
Vermessungswesen
Notifizierte Stelle NB 0445

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Requirements for conformity assessments and terms and conditions for certification

for conformity assessments in accordance with Regulation 2016/425/EU on personal protective equipment

1 Preliminary remarks

This document is divided into a presentation of the requirements for successfully completing a conformity assessment in accordance with Regulation EU 2016/425 on personal protective equipment (PPE) (Sections 2 and 3), the certification conditions (Section 4) and legally binding information and complaints (Sections 5 and 6). By assignment of the Notified Body of the BEV (also when submitted by the authorised representative), the manufacturing company acknowledges these requirements, certification conditions and information.

2 General requirements for conformity assessments

2.1 Application

The application is to be submitted by

- the manufacturer

- a representative based in the European Union[1] and authorised by the manufacturer for this task

In the case of an authorisation, the following is also required:

- A written authorisation issued by the manufacturer to a natural or legal person established in the Member States, clearly stating the tasks assigned to the representative
- Any previous authorisation must be revoked at the same time
- A declaration by the authorised representative to cover all costs of the conformity assessment procedure(s).

The authorised representative must assume the obligations set out in Regulation EU 2016/425 on personal protective equipment.

The application must contain:

- Name and address of the manufacturer and, if the application is submitted by the authorised representative, also his 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
- Consent to fulfil the obligations imposed by Regulation 2016/425/EU, the General Terms and Conditions (GTCs) ("Allgemeine Geschäftsbedingungen") of the Notified Body of the BEV and the terms and conditions for certification outlined in section 4, and to provide the information required for this purpose
- The module-dependent information listed in section 3

2.2 Fees and charges

The fees set by the BEV in accordance with § 62 b Para. 2 of the Measures and Verification Act (MEG) BGBl No. 152/1950, as amended, for carrying out the conformity assessment procedure are to be paid by the applicant.

The expenses incurred during the technical testing of a product or during the performance of audits are charged separately by the physico-technical testing service („Physikalisch-Technischer Prüfdienst (PTP)") of the BEV. Quotations can be requested from the PTP in advance.

[1] In the following, the European Union refers to the member states of the European Union, the signatory states of the EEA and Switzerland.

2.3 Technical documents

The technical documentation must be submitted with all applications. The notified body of the BEV may request further copies of the documentation if necessary. The technical documentation to be drawn up by the manufacturing company must be in accordance with Annex III of Regulation EU 2016/425:

a) A complete description of the PPE and 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 applicable to the PPE;
d) Design and manufacturing drawings and corresponding plans of the PPE, its components, assemblies and circuits;
e) Descriptions and explanations necessary for the understanding of the drawings and diagrams referred to in point (d) and the functioning of the PPE;
f) The references of the harmonised standards referred to in Article 14 of Regulation EU 2016/425 which have been applied in the design and manufacture of the PPE. In the case of partial application of harmonised standards, the technical documentation shall specify the parts which have been applied;
g) where harmonised standards have not been applied or have been 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 determine the relevant protection class;
j) A description of the means used by the manufacturer during production to ensure 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 of Regulation EU 2016/425;
l) For PPE produced as a single unit to fit an individual user, all 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 for 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 Module-specific provisions

The basic principles of the module procedures, the required documents and the key information and retention obligations are described in Annexes IV to VII of Regulation EU 2016/425. The requirements described below are based on this legal document.

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 of the planned production must be submitted together with the application. The notified body may request further samples if necessary for the implementation of the test programme. In the case of PPE manufactured in series, where each individual item is customised for an individual user, samples representative of the range of different users must be supplied. In the case of PPE that is customised for an individual user, a basic model must be supplied.

3.1.2 Maintenance of the certification

The documents on which the certification is based are kept by the Notified Body of the BEV. The notified body must be notified 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. For extension of an EU type-examination , the application forextension shall be submitted at the earliest 12 months and at the latest 6 months before the expiry date of the EU type-examination certificate.

If the notified body becomes aware of defects in products placed on the market, it shall inform the manufacturer and request corrective action by a specified date. In the event of systematic non-compliance with the requirements of Regulation EU 2016/425 despite a request from 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 is published on the BEV homepage, communicated 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 BEV homepage.

3.2 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 documents listed in section 2.3, the application must include the following documents:

a) Identification of the PPE concerned/scope of certification requested
b) copy of the EU-type examination certificate (if the notified body selected is not the notified body that carried out the EU-type examination)
c) a declaration concerning the measures taken to ensure that the manufacturing process and its monitoring guarantee the uniformity of manufacture and the conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of Regulation EU 2016/425.
d) Contingently, sample form and sample declaration of conformity (not mandatory)

3.2.2 Procedure

The procedure essentially follows these steps:

1. Application for assessment and submission of the documents by the manufacturer or the authorised representative (hereinafter referred to simply as the "manufacturer")
2. After the application has been reviewed, the notified body sends the draft surveillance contract to the manufacturer.
3. Document review, requests for missing documents, if necessary
4. Conclusion of the surveillance contract
5. First product tests no later than one year after the date of issue of the type examination certificate.
6. Annual sampling (at random intervals) for product checks to determine whether the uniformity of manufacture is ensured and the products comply with the essential health and safety requirements

3.2.3 Maintenance of the certification

The validity of the certificate of module C2 is linked to the validity of the type examination certificate. The list of documents on which the certification is based is kept by the notified body of the BEV. The notified body must be notified of any changes to the content of these documents or to the type itself that affect the conformity of the products, the scope of certification or its framework conditions. If necessary, a revision procedure will be initiated. If the notified body becomes aware of deficiencies in products placed on the market, it shall inform the manufacturer and request corrective action by a specified date. In the event of

systematic non-compliance with the requirements of Regulation EU 2016/425, the notified body may withdraw the certificate

3.3 Conformity to type based on quality assurance of the production process (Module D)

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

3.3.1 Application

In addition to the information listed in section 2.1, the application must include the following documents:

a) the address of the manufacturer's premises where the audits can be carried out;
b) the identification of the PPE concerned;
c) the documentation concerning the quality assurance system.

If the notified body selected is not the notifed body that carried out the EU type-examination, the application must also include the following:

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

3.3.2 Documents of the quality assurance system

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

The documentation of the Quality assurance system must contain an appropriate description of the following points in accordance with Annex VIII Module D, Regulation EU 2016/425 on personal protective equipment:

- Quality objectives and organisational structure, responsibilities and powers of management with regard to product quality;
- The corresponding manufacturing techniques, procedures and systematic measures for production, quality control and quality assurance;
- Tests and inspections carried out before, during and after manufacture, with an indication of their frequency;
- Quality records such as test reports, test and calibration data and reports on the qualifications of the staff employed in this area, and

- Means of monitoring the achievement of the required product quality and the effective operation of the quality assurance system.

The documentation typically includes (but is not necessarily limited to):

- Quality management manual
- Organisation charts
- List of staff including their responsibilities
- Proof of competence of employees working in this area
- Process and work instructions
- Details on the means of monitoring product quality
- List of measuring instruments used
- Copies of EU type examination certificates
- Sample declaration of conformity
- Proof of ISO/IEC 9001 certification, if applicable

3.3.3 Evaluation of the quality assurance system: procedure

The key points of this procedure are as follows:

1. Application for assessment of the quality assurance system and submission of the documents by the manufacturer or the authorised representative (hereinafter referred to simply as the "manufacturer")
2. After review 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 in such as to ensure an impartial procedure. The manufacturer has the possibility to object to the appointment of the auditors.
3. Document review, if necessary additional request for missing documents by the audit team
4. Stage 1 audit: Obtain sufficient knowledge and scope of the management system to plan the main audit focus (Stage 2). Important topics: Mapping of the specific requirements of Regulation 2016/425/EU, the harmonised standards or normative documents and, if applicable, specifications in the EU type examination certificates in the management system and its processes. If applicable, when the management system is newly introduced (i.e. certification according to ISO/IEC 9001 is not available), the progress of the introduction and the preparation on the part of the personnel is assessed in order to plan the time of 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 found to be non-compliant in the main audit.
5. Incorporation of the findings from the stage 1 audit by the er
6. Sending an audit plan, making an appointment for the stage 2 audit

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 Regulation 2016/425/EU, the applicable harmonised standards, normative documents and, if applicable, specifications in the EU type examination certificates. The main audit is documented in the audit report.
8. Rectification of any findings by the manufacturer and verification of the rectification by the audit team
9. Issuing of the certificate of the assessed quality system and authorisation to affix the notified body's identification number to the compliant products.

The certificate of the approved quality assurance system is valid for a period of 3 years from the date of the certification decision. The list of documents on which the certification is based is kept by the notified body of the BEV. The notified body must be notified of any changes to the content of these documents and to the quality assurance system itself that affect the conformity of the products, the scope of certification or its framework conditions. If necessary, a revision procedure will be initiated.

3.3.4 Maintaining and expanding certification

The notified body carries out one announced audit per year and, before the certificate expires after three years, a re-certification audit to ascertain itself that the manufacturer is applying and updating the quality assurance system. The first surveillance audit is carried out within 12 months of the first certificate being issued. Inspections can also be carried out without prior notification. Full or partial audits can be carried out during these inspections. The manufacturer receives an inspection report and, if applicable, an audit report.

If the notified body becomes aware of deficiencies in products placed on the market, it shall inform the manufacturer and request corrective action by a specified date.

Certification will be suspended if:

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

The verification of the rectification 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 rectified within the specified period, recognition is restricted or withdrawn.

4 Terms and Conditions for Certification

The manufacturer shall ensure that:

- Declarations of certification are only made 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 unauthorised;
- After suspension or withdrawal of certification (whatever the cause), all advertising relating to the certification in any way is discontinued and all certification documents required by the Notified Body of the BEV are returned;
- No certification document, certification marking or report or part thereof is used in a misleading manner;
- Copies of the certification documents are only reproduced and passed on to third parties in their entirety;
- The requirements of the notified body of the BEV are fulfilled, if 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 that these records are accessible to the Notified Body of the BEV upon request;
- Appropriate measures are initiated and documented with regard to such complaints, and with regard to all defects found in products that affect the fulfilment of the certification requirements;
- The notified body of the BEV is informed of all relevant changes that may affect the conformity of the product (e.g. the intended modification of the product, changes to the manufacturing process or the quality assurance system). The notified body determines whether the announced changes require further investigations. Certified products resulting from such changes may only be released once the notified body of the BEV has notified the manufacturer accordingly.

Any use of BEV symbols, marks or logos requires the written authorisation of the BEV. Reference to certification and the use of symbols is possible:

a) in correspondence (within the scope of the certification)

b) in publications (not on business cards)

Reproduction of documents of the notified body of the BEV relating to the certification that is separate from a correct reproduction is not permitted. It is not permitted to print or reproduce only extracts of the certification documents for forwarding to third parties.

5 Management of Information

The management and employees of the Notified Body are bound to official secrecy on the basis of the statutory provisions with regard to all information of which they become aware in the course of carrying out their tasks within the framework of the EU Directives.

The Notified Body of the BEV is obliged to make the documents on which the recognition is based available to a member state at the request of that state. In addition, information obtained from the conformity assessment procedures is only passed on to third parties with the prior consent of the applicant(s).

EU type-examination certificates and certificates of approved quality assurance systems as well as related amendments (revisions) are published (excluding the technical annexes) in the Official Journal of Metrology and on the BEV website (www.bev.gv.at). All other information from conformity assessment procedures is treated confidentially and protected against unauthorised access. If further information is made publicly accessible by the notified body due to legal obligations, the applicant will be informed in writing.

The manufacturing companies will be informed in writing of any changes to the requirements by the notified body of the BEV.

6 Treatment of complaints

Complaints in terms of the EN/ISO 17065 standard are handled in accordance with the provisions 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 conclusion of the complaint.