TESTEX®

Content

1. General information for applicants

With this documentation we provide you with the basic information necessary for certification. For further information, please do not hesitate to contact us.

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2. Duties of the certification body

The certification body of TESTEX AG is obliged to operate a certification scheme suitable for the accredited area. The basis of certification is a legally enforceable certification agreement. Typically, this is available in the form of a signed offer as well as a completed application form.

The certification body shall make provisions to comply with the requirements according to ISO 17065 regarding evaluation, assessment, surveillance as well as documentation review. The complaints procedure shall be accessible and transparent.

The certification body is obliged, as far as permissible, to provide further information on the planned certification on request.

3. Obligations of the applicant

Both product requirements and requirements for the applicant must be fulfilled.

For a detailed description of the obligations, see Chapter III of Regulation EU 2016/425, Article 8: Obligations of manufacturers, Article 9: Authorised representatives, Article 10: Obligations of importers and Article 11: Obligations of distributors as well as ISO 17065:2012, Chapter 3.7.

The applicant is obliged to place on the market only PPE which has been designed and manufactured in accordance with the essential applicable health and safety requirements (Annex II Regulation EU 2016/425).

With suitable quality management procedures, you can ensure that the conformity of the manufactured PPE is guaranteed at all times in series production.

Requests for changes are to be reported to the certification body at an early stage. In the case of a positive assessment, these can be confirmed as compliant with a confirmation letter, a supplement to the certificate or a new certification, depending on change request. Changes that have been unintentionally introduced to the PSA and have been discovered internally must be reported immediately to the certification body, which will decide on the further measures to be taken, see point 13.

Changes that could affect the ability to meet the certification requirements, for example due to changes in personnel or change of assemblers, shall also be reported immediately to the certification body.

The certification is not to be used improperly; in particular, no misleading or unjustified statements are permitted in this context.

4. Application for certification

The application must be made using the application form, which can be obtained from the TESTEX AG website. The requirements according to Regulation EU 2016/425 Annex V, point 3 and ISO 17065:2012, Chapter 7.2 Application apply.

5. Application evaluation

The certification body carries out an application evaluation to assess the application and the information provided. Among other things, this ensures that the following requirements are met for the planned certification:

Applicant

- Sufficient information provided by the applicant
  - Application form filled in completely and meaningfully
  - Signed declaration of commitment
  - Existing technical documentation
- Assessment of QM processes and PSA knowledge

Certification body

- Ensuring impartiality
- Appropriate scope
- Resources available for the implementation of the certification
- Existing skills and competences

In case of rejection, the applicant will be informed in writing, usually by email, stating the reasons. If the assessment is positive, the certification process can be initiated.

6. Evaluation

The certification body of TESTEX AG uses evaluation plans which are developed on the basis of Regulation EU 2016/425 and the specific requirement standards. Requirements according to ISO 17065, chapter 7.4 Evaluation must be fulfilled. The certification body of TESTEX AG accepts test reports from ISO 17025 accredited testing laboratories that are no more than 5 years old. You can also have the tests organised by our account managers, in which case we are responsible for compliance with the requirements for the evaluation results.

The existing evaluations are recorded by the certification body of TESTEX AG. Missing and/or incorrect test reports are noted and you are notified in writing.

7. Subcontracting

If you wish to organise the evaluation by our account managers, these will be carried out as a subcontract. For organisational reasons, an evaluation at the TESTEX AG testing centre is also to be understood as a subcontract. The signed quotation is deemed to be a declaration of consent for the subcontracting of an evaluation. The applicant may make requests regarding the testing laboratory performing the evaluation, but the requirements set out in point 6 Evaluation must be observed. Any additional costs incurred as a result will be borne by the applicant.

8. Evaluation

Assessment of the evaluations is carried out by experienced, trained staff of the certification body who have been approved for this work. The results obtained from the evaluation are compared with the requirements from the standards and the performance of the present PSA is assessed.

If a requirement point is not fulfilled, we will contact you in writing and discuss the further procedure.

If all points of the evaluation can be positively assessed, they are summarised and documented in an evaluation report.

9. Certification decision

In order to make the certification decision, the documentation is subjected to a second check. The person making the certification decision must not have been involved in the assessment process. The certification body of TESTEX AG is solely responsible for the certification decision.

Negative decisions are communicated in writing, stating the reasons. In the case of a positive decision, the documentation is released for signing and thus the certificate issuance is initiated.

10. Certification documentation

The applicant is issued with documentation consisting of an assessment report and a certificate when the certificate is granted. The certificate consists of the following elements, among others:

- Name, address and identification number of the certification body
- Name and address of the applicant
- Date of issue and expiry and, if applicable, date of amendment
- Scope of certification
- Further information on the certified PPE
- Signature of an authorised person

11. Directory of certified products

The certification body shall maintain a list of certified products in the form of a database. This contains, among other things:

- Article description
- Certificate number
- Scope
- Date of issue

The list is not public.

12. Monitoring

If PPE of class III is involved, a surveillance of conformity according to Regulation EU 2016/425 Annex VII, Module C is foreseen. For this purpose, a contract for the surveillance activity will be sent to you together with the certificate and the assessment report when the certificate is issued. This must be returned within a reasonable period of time, as a rule within 10 working days at the latest. Non-returned contracts may lead to consequences according to point 14.

As a rule, the monitoring shall take place annually. For this purpose, the certificate holder or the authorised body receives an invitation letter. This letter contains all certificates due for surveillance and an invitation to report for the purpose of scheduling surveillance.

If delays occur in the monitoring activity, the examined attributes are adjusted to the extended time period.

Monitoring, or sampling for monitoring, is preferably carried out by our staff on site. Monitoring via remote channels is also permissible.

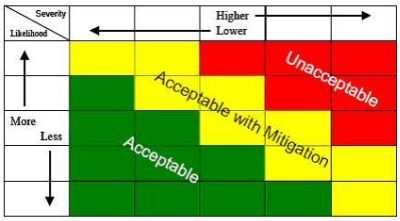
The following options are available for the affected certificates:

Stock items
Sample name possible.

Customised goods
In the case of non-stock items, you are obliged to ensure sufficient surplus production when production takes place and to make this available to the certification body for the purpose of surveillance activities. You can do this without our request during the year or hand over the PPE during our regular inspection. In the case of surveillance activities with >1 year intervals between the surveillances, the examined attributes are adjusted to the extended time period.

No production
If no production has taken place, no monitoring can take place. If monitoring takes place at a later date, the number of attributes to be examined will be adjusted. If there are indications that production has taken place despite claims to the contrary, measures can be initiated, see point 13.

The tests to be performed are selected according to a risk-based approach. Our experienced and trained staff review the PSA received and, based on the initial assessment, select audits from the evaluation plan that represent the highest risks according to probability of occurrence and impact.



Audits are usually alternated during the period of validity so that significant risks have been examined during the period of validity.

Any non-conformities detected shall be notified to the certificate holder in writing. Two different levels of non-conformities are distinguished:

- Minor non-conformities
- Major non-conformities

Minor non-conformities
Non-conformities from which a limited risk arises. These can be, for example, formal errors such as missing year numbers for the standards in the label.

Major non-conformities
Non-conformities that cause the PPE to pose a risk. Usually material or fabrication defects or problems.

In the event of non-conformities being discovered, considerations of the following questions, among others, are important:

- **Is faulty PPE already in circulation?** If so, how it will be removed from circulation and, if necessary, restored to proper condition.
- **Is defective PPE in stock?** (In the warehouse of all parties involved, incl. intermediaries) If yes, check and take remedial action so that it is restored to proper condition.
- **How can the processes be improved so that the occurrence of the error can be avoided?** Identify the faulty processes and take corrective and improvement measures to avoid future deviations of the same kind.

The written notices contain deadlines. If these deadlines cannot be met, the certification body of TESTEX AG must be informed in sufficient time before the deadline expires. If the applicant is unable or unwilling to respond to the non-conformities discovered, or if the deadlines are not met without comment, measures may be taken in accordance with point 13. If there is a corresponding risk potential of non-conformity of the PSA, SECO as well as the participants of VG5 may be informed.

If the monitoring is completed positively, you will receive a report summarising the examinations carried out and their results.

13. Termination, restriction, suspension or withdrawal of certification

The regular termination of a certification occurs when the validity period expires. The validity period of certificates is 5 years, whereby the mode is analogous to many official documents: date of issue + 5 years - 1day.

Termination, restriction, suspension or withdrawal of certification may also be initiated due to non-conformities. This can be done by the certification body as well as at the request of the applicant if the applicant identifies risks.

Non-conformities detected during monitoring activities are also among the possible reasons for the above-mentioned action.

In the event of termination, restriction or suspension of the certificate due to non-conformities, a report can be made to VG5 members or the market surveillance institutions, in Switzerland SECO.

In the event of termination, restriction, suspension or withdrawal of certification, all public information shall be amended in such a way that it is clear which scope currently applies.

14. Records

The certification body of TESTEX AG shall retain all records relating to the certification process for 15 years. All records are treated confidentially.

15. Complaints and appeals

Complaints and appeals will be accepted in writing. For this purpose, the email address ppecomplaints@testex.com is available. Using this email address ensures that all employees responsible for complaints management are informed and that the complaints process can be initiated.

If you do not agree with the outcome of the complaint process or the general procedure, you can submit a petition to the President of the Independent Steering Committee of TESTEX Product Certification, Mr Adrian Blumer:

Mr Adrian Blumer
Forensic Institute Zurich
PO Box
8010 Zurich
adrian.blumer@for-zh.ch

16. Documents required from the applicant

The detailed description of the technical documentation to be submitted can be found in Regulation EU 2016/425 Annex III. The specific requirements can be found in the requirement standards. A reference source for standards can be, for example, the online shop of the Swiss Association for Standardisation (SNV): https://connect.snv.ch/de/

The technical documentation shall include in particular:

- Completed and signed application form and declaration of commitment
- Construction drawings, design and manufacturing sketches
- Existing test reports for all materials used (textiles, fasteners, hardwear, etc.). A maximum of 5 years old reports from a test institute accredited according to ISO 17025 or valid OEKO-TEX® certificates for proof of harmlessness are accepted.
- Labels and manufacturer information
- QM documentation of the applicant and, if different from the applicant, of the executing fabricators. This can be, for example, an ISO 9001 or comparable certificate.

17. Document formats

MS Office or pdf files are preferred.

18. Languages

Usually German or English, other languages by arrangement.

19. Assistance

We are happy to answer detailed questions on the procedure, processes and precise interpretations of the standards and/or Regulation EU 2016/425. We reserve the right to charge for this if a certain amount of work is involved. We will contact you in this case.

In order to maintain integrity and independence, consultancy in the sense of participation in the development, manufacture, installation or distribution of a certified product or product to be certified is not permitted and shall not be offered or provided (ISO 17065:2012 7.2.6).

20. Costs

The costs for the planned certification are quoted according to the expected expenditure in the individual case and consist of:

- Certificate fee 500.-
- Report fee 60.-
- Effort 120.-/h

Due to their large number, the costs of tests incurred cannot be fully recorded. These are available on request.

For category III PPE, monitoring costs continue to be incurred. These depend on whether any retesting, further examinations or certificate supplements are necessary and cannot be estimated in advance.