Certification Programme

(Product Certification Programme)
for Personal Protective Equipment (PPE)

PPE Regulation (EU) 2016/425
(Module B, Module C2 , Module D)
EN ISO/IEC 17065
EN ISO/IEC 17067

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Preface

The overall goal of certification is to give all parties the confidence that a product meets the requirements set out by law and the relevant harmonised or non-harmonised standards and/or technical specifications and/or directives.

The certification*) of personal protective equipment (PPE) is carried out in accordance with Regulation (EU) No 2016/425.

*) "Certification" is a particular form of conformity assessment.

The "PPE Regulation (EU) No. 2016/425" is the basis for placing PPE on the market throughout the EU.

In order to carry out the necessary conformity assessment*) (= certification), independent third parties are required (= Notified Bodies = NB). The OETI has been a notified body for PPE since 1995 (identification number 0534).

*) A "conformity assessment" is the procedure used to assess whether the essential health and safety requirements for PPE, as set out in Regulation (EU) 2016/425, are met.

This certification program describes

- Module B: Conformity assessment procedure according to Module B (EU type examination) in accordance with Annex V of the PPE Regulation for PPE categories II and III.
- Module C: internal production control (for categories I, II and II: Module C in accordance with Annex VI of the PPE Regulation; to be carried out by the manufacturer))
- Modul C2: periodic supervised product testing in accordance with Module C2 (for Category III; conformity to type based on internal production control with supervised product testing at irregular intervals) in accordance with Annex VII of the PPE Regulation
- Modul D: recurrent monitored quality assurance related to the production process according to Module D (for Category III; conformity to the type based on quality assurance related to the production process) according to Annex VIII of the PPE Regulation.

Risk categories of PPE (as per PPE Regulation (EU) No 2016/425, Chapter IV; Article 18 and Annex I)

Category I only applies to the following minor risks:

a) superficial mechanical injuries;
b) contact with weakly aggressive detergents or extended contact with water;
c) contact with hot surfaces which do not exceed 50°C in temperature;
d) damage to the eyes caused by solar radiation (except when directly observing the sun);
e) weather conditions which are not of an extreme nature.

Category II includes risks which are not listed under Category I or Category III;

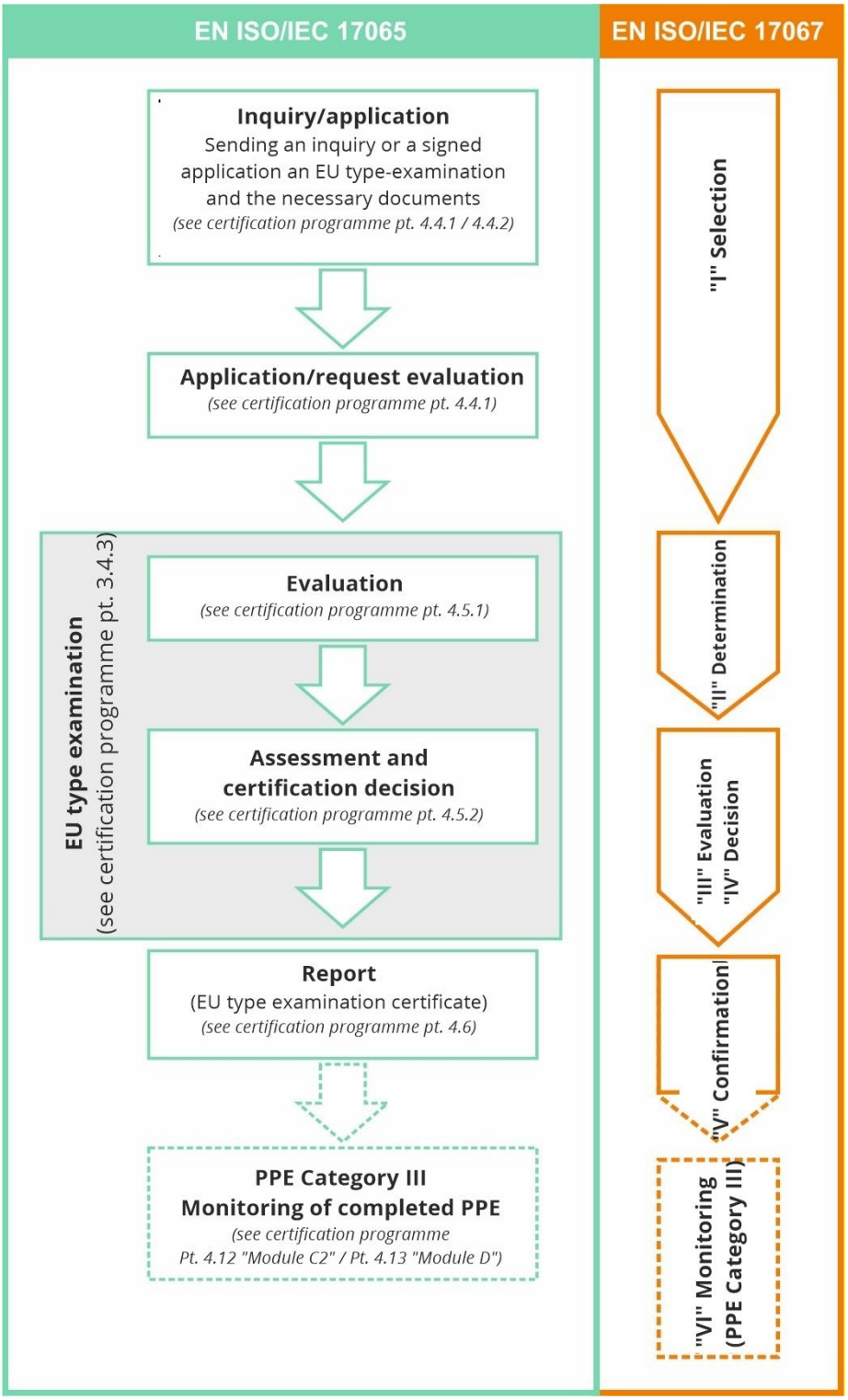
Category III applies only to risks which may incur very serious consequences, such as death or irreversible damage to health associated with:

a) substances and mixtures hazardous to health;
b) atmospheres with a lack of oxygen;
c) harmful biological agents;
d) ionising radiation;
e) a warm environment with an effect comparable to that of an environment with an air temperature of 100°C or above;
f) a cold environment with an effect comparable to that of an environment with an air temperature of -50°C or lower;
g) falling from heights;
h) electric shocks and working on live parts;
i) drowning;
j) cuts caused by hand-held chainsaws;
k) high pressure jets;
l) injuries caused by projectiles or knife wounds;
m) harmful levels of noise.

The EU type-examination certificate together with the EU Declaration of Conformity *(Note: before drawing up the EU Declaration of Conformity, the manufacturer must carry out an internal production control on the manufactured products in order to ensure the conformity of his product with the EU type approved according to Module B)* and, in the case of PPE of category III, a supervised product test at irregular intervals (Module C2) or a quality assurance related to the production process (Module D) entitles the manufacturer to affix the CE marking to the respective PPE.

The path to certification of PPE Category II and Category III at a glance

"PLAN FOR EVALUATION ACTIVITIES"



1. Terms

Type
"Type" refers to a model of PPE that is subject to an EU type examination.

EU type examination certificate
If the type complies with the applicable basic health and safety rules, the notified body shall issue an "EU type examination certificate" to the manufacturer

EU type examination
EU type examination is the part of a conformity assessment procedure described in Regulation (EU) 2016/425, in which a notified body (OETI) examines and verifies the technical design of a PPE and certifies that the requirements are met.

Conformity assessment
The term "conformity assessment" indicates the procedure used to assess whether the essential health and safety requirements for PPE set out in Regulation (EU) 2016/425 are met.

Certificate
The term "certificate" is not included in Regulation (EU) 2016/425. A "Certificate of EU type examination certificate" is a document issued in addition to the "EU type examination certificate", which is an abridged version of the result of the type examination. This "Certificate of EU type examination certificate" does not replace the "EU type examination certificate" and only serves to provide a clear document for distribution.

Certification
A "certification" is the process of conformity assessment. In the following text, the terms "certification" - "conformity assessment" - "EU type examination" are used as equivalents.

Certification body
"Certification body" refers to a conformity assessment body which carries out EU type examinations and is not affiliated with the contracting entity as an "independent third party".

2. Objectives and scope

The aim of the certification programme (product certification programme) is to describe the certification system used in the OETI. This certification system is the basis for the certification of personal protective equipment (PPE)

This description is the basis of implementation for the certification of personal protective equipment (PPE) in accordance with Regulation (EU) 2016/425 (formerly in accordance with Directive 89/686/EEC), which is included in the scope of accreditation of the OETI (notified body NB 0534).

Unless otherwise stated, the procedures described in this document refer to all standards and products included in the scope of accreditation.

3. General

3.1. Requirements for a certification body

The general requirements for a certification body are defined in EN ISO/IEC 17065 Section 4. The fulfilment of and compliance with the requirements is overseen and monitored by an accreditation authority (Akkreditierung Austria).

Thus, the following points dealt with in EN ISO/IEC 17065 section 4 are taken into account:

Pt. 4.1 Legal and contractual matters
- The certification body is a legal entity
- The certification agreement contains all the required information (see corresponding applications for the issuance/amendment/supplement/extension of an EU type examination certificate)
- The use of permits, certificates and conformity marks

Pt. 4.2 Handling impartiality
Pt. 4.3 Liability and financing
Pt. 4.4 Non-discriminatory conditions
Pt. 4.5 Confidentiality
Pt. 4.6 Publicly available information

3.2. Access to the certification programme

The certification programme is made available to OETI customers both actively (where it is sent out in the event of changes) and upon request.

3.3. Impartiality

All certification actions are carried out impartially. The senior management of the certification body is obliged to be impartial.

The impartiality of the certification body is assessed in the annual management review and ensured by the governing committee of the certification body.

If the impartiality of an employee of the certification body is not guaranteed, the affected employee will be excluded from the relevant certification process.

3.4. Non-discriminatory conditions

If the requested services are included in the certification programme of the certification body, all services offered by the certification body will be made available to all applicants.

3.5. Publications and confidentiality

The certification body is obliged to record the following information about the certified products' protection

a) identification of the product;
b) the standard(s) and other normative documents according to which conformity has been certified;
c) identification of the customer.

A non-public list "Overview of type examinations" " is maintained to record this information.

The OETI does not publish any of this information, but upon request, it will confirm the validity of a specific certificate (= "EU type examination certificate"). In addition to this, and in the interests of confidentiality*), no information relating to the content of the type examination certificate or associated documents and samples will be passed on without the customer's prior approval.

The customer is informed of these facts as part of the type application.

*) *Explanation of "Confidentiality"*
The certification body undertakes to consider all information received or created during the certification process as protected and confidential (in accordance with the General Terms and Conditions of Services). Without prior approval by the customer, no content will be made publicly available by the certification body or passed on to third parties.
Exceptions to this are

- *information that the customer themselves makes available to the public or*
- *if there is an agreement between the certification authority and the customer for publication.* or
- *information that must be disclosed due to legal requirements or passed on to responsible organisations (e.g. Akkreditierung Austria) and/or persons (e.g. experts within the field of accreditation).*

3.6. Rights and obligations of the owner of the certification programme

The owner (= programme owner) of this certification programme is the "OETI - Institut fuer Ökologie, Technik und Innovation GmbH" (hereinafter referred to as "OETI").

The certification programme was developed for sole usage by its customers.

The management of the certification body is responsible for the creation, objectives, content and completeness, as well as the maintenance of this certification programme.

OETI employees are obliged to maintain the confidentiality of data, results, and information obtained in the course of their testing and certification activities. This ensures that the confidentiality of all information is protected.

3.7. Costs

The costs incurred for carrying out an EU type examination in order to obtain an EU type examination certificate will be communicated to the customer upon request.

3.8. Responsibility/liability of the certification body

The certification body is responsible for the proper execution of the evaluation/assessment and certification decision, as well as the certification programme.

The certification body is only liable to the applicant or third party if intent or gross negligence can be proven. The product certification body shall not be liable for any disadvantages that the applicant may incur as a result of refusing an EU type examination certificate on the basis of a negative test report or a negative certification decision.

3.9. Procedure for customer complaints (grievances) and objections

Customer complaints (grievances) and objections must be submitted in writing to the management of the certification body and are handled by an internal complaint procedure.

4. Certification programme

Requirements

The basis of the requirements against which the products are evaluated are expressed in Annex A. If necessary, the requirements can be specified and made available in more detail (upon request).

All other requirements not contained in the relevant requirements standards which must be met are contained in Regulation (EU) 2016/425.

An overview of this, as well as further information required for certification, can be found in the overview in Annex B.

General conditions

The conditions for granting, renewing, and extending the scope of application can be found in the certification agreements included in the corresponding application. (The certification agreement is included in the corresponding application form and published on the OETI homepage).

Any obligations to be fulfilled in the event of "termination, restriction, suspension or withdrawal of certification" are included in the relevant application form and explained in the section "Termination, restriction, suspension or withdrawal of certification".

Requirements for certification bodies and other conformity assessment bodies

The requirements for the certification body are defined by various standards (EN ISO/IEC 17065). The fulfilment of these requirements is overseen, monitored and confirmed by the accreditation authority (Akkreditierung Austria).

No other conformity assessment bodies are involved in the certification activities carried out by the OETI (Notified Body NB 0534).

Resources

The resources necessary for the implementation of the programme, including impartiality and competence of staff (both internal and external) and for evaluation, are available as defined in the OETI quality management system.

Participation in specialist committees (e.g. standardisation committees) as well as the possibility of feedback and suggestions for improvement from customers ensure ongoing development and its review.

Furthermore, the competence of the employees is ensured by participation in Horizontal Committee Meetings and Vertical Group Meetings (e.g. VG 5: Protective Clothing including Gloves).

Record-keeping

Records are kept for at least 5 years after the end of the product's placement on the market (or after termination of the monitoring contract).

4.1. Development of the certification programme and certification process

The content of the certification programme is developed in line with the products included in the certification programme (see Annex A) and specific standard requirements *)

A review of the topicality of the programme is carried out within the scope of scheduled internal audits and external audits by the accreditation authority (Akkreditierung Austria).

*) *The list of applicable standards is published in the Legal Information System of the European Union, in the official Journal of the European Union. We would be happy to send the link to the current document upon request*

The general procedure of certifications (= certification programme) for **Category II** and **Category III** PPE is set out in Annex C and includes the following steps:

I.	Selection	=	the actions to obtain all the information needed for the subsequent investigation
II.	Investigation	=	conformity assessment actions (e.g. testing, measuring, inspection) to obtain information on product requirements as a basis for assessment and confirmation;
III.	Assessment	=	verification of suitability with a view to meeting specified requirements;
IV.	Decision	=	on certification;
V.	Confirmation	=	issuing a conformity statement based on the previous steps
VI.	Monitoring	=	systematic repetition of conformity assessment activities as a basis for maintaining the validity of the conformity statement (if necessary),

The certification of products is always based on a certification programme.

4.2. Required information and samples

In order to carry out a certification, the applicant shall provide the certification body with the following information:

I. at least one complete version of the PPE (= a ready-made sample)
II. the technical documentation referred to in Regulation (EU) 2016/425

The validity of the submitted test reports for the materials used is the responsibility of the applicant.

4.3. Recognition of results

Only test reports which meet the following criteria can be considered in the certification process.

I. Test reports must be **prepared by an accredited testing laboratory**
II. Test reports **must not be older than 5 years**
III. If test reports contain **information about the measurement uncertainty**, the "Simple Acceptance Rule" is adopted as the basis for decision-making, i.e. the measurement uncertainty is not taken into account for the conformity statement.

4.4. Steps to obtain an EU type examination certificate (in accordance with Regulation (EU) 2016/425 Module B; includes the draft)

4.4.1. Application/request evaluation

Procedure for unknown regulations/new customers:

If the submitted application/request requires certification according to unknown requirements, it is assessed whether the certification body has the necessary competence and ability to carry out the certification actions. The impartiality of the certification body in relation to the new customer/applicant is also assessed.

If the **impartiality** as well as the **competence and ability** for the actions relating to certification ...

- **are given,** the application is **accepted**
- **are missing,** the application is **rejected**

In both cases, the customer will be informed in writing (informally).

In both cases, records are kept documenting the reasons for the decision to either confirm or reject the certification.

Procedure for familiar requirements/existing customers:

If an application/request for certification is submitted/commissioned/requested by a known customer and according to already known requirements, no special competency assessment is required, but the impartiality of the certification body in relation to the customer/applicant will still be assessed.

4.4.2. Applications/contracts

The basis of certification is the sending of a signed application for the issuance of a type examination certificate for personal protective equipment (PPE).

Customers who order certification of personal protective equipment (PPE) are informed about the 'Certification Agreement' as part of the application forms. The certification agreement complies with the requirements of EN ISO/IEC 17065:2013 and contains detailed information on the rights and obligations of the applicant and the certification body.

By signing the completed application form and thus the respective valid certification agreement, this and the certification programme cited therein are accepted by the client. This is documented by the signature of an authorised signatory with the applicant's company stamp.

The application forms are published on the OETI homepage.

4.4.2.1. New applications for an EU type examination certificate

For the purpose of issuing an EU type examination certificate, an application form is provided to the applicant (manufacturer/authorised representative/importer/distributor) by the certification body.

The form "Application for the issuance of an EU type examination certificate" must be completed and signed in full. The application shall be joined by the documents and specimens referred to in the application form.

The steps described in "Annex C – Certification Procedure" are carried out.

In the course of processing a new application, a project number (e.g. VN635 186940) and a contract number (e.g. VN635 186940.1) will be assigned. This project number is also the number of the "EU type examination certificate"

4.4.2.2. Application for an amendment/extension of an EU type examination certificate

In the event of a necessary/desired modification/extension of an EU type examination certificate, the applicant (manufacturer/authorised representative/importer/distributor) will be provided with a corresponding application form by the certification body.

The cases listed in pt. "3.4 Validity in accordance with Regulation (EU) 2016/425", which require a new review, must be considered.

From the first application, the customer is informed that all changes affecting the certification , must be reported and that an application for a "change or extension of an EU type examination certificate" must be made in writing. The corresponding form must be completed and signed in full. The application shall be joined by the documents and specimens referred to in the application form.

In the course of processing an amendment/extension, the number of the "EU type examination certificate" remains unchanged and a new application number will be assigned

The steps described in "Annex C – Certification Procedure" are carried out.

4.4.2.3. Application for the extension of the validity of the EU type examination certificate

In the event of an extension of the validity of the EU type examination certificate, the applicant (manufacturer/authorised representative/importer/distributor) will be provided with a corresponding application form by the certification body.

The deadline requirement specified in pt. "3.4 Validity in accordance with Regulation (EU) 2016/425" (at the earliest twelve months and at the latest six months before the expiry of validity) must be taken into account

If the application for renewal is submitted only after the expiry of the validity of the "EU type examination certificate", a new examination is carried out under a new project number (= number of the "EU type examination certificate").

The application must be made in writing. The corresponding form must be completed and signed in full. The application shall be joined by the documents and specimens referred to in the form.

The process is also analogous to a new application. The steps described in "Annex C – Certification Procedure" are carried out.

In accordance with Regulation (EU) No 2016/425 (pt. 7 "Verification of the EU type examination certificate"), the extension of validity is subject to the possibility of "carrying out a simplified verification procedure to extend the validity of the EU type examination certificate", if the following conditions do not apply

a) Where there is an amendment to the approved type (e.g. an amendment to the approved type, or to any materials, components, or assemblies used), or

b) in the event that the state of technology develops

Whilst processing an extension, the number of the "EU type examination certificate" remains unchanged and a new application number is applied.

4.4.2.4. Excerpt from an EU type examination certificate

Upon request, an excerpt from an EU type examination certificate can be ordered. No formal application is required to commission the preparation of the extract, but in any case the application must be made in writing..

As this document is not an independent EU type examination certificate, no new certification process is required.

When an extract is issued, the number of the "EU type examination certificate" remains unchanged and a new order number is assigned.

4.4.2.5. Contract for the monitoring of the finished PPE in accordance with Regulation (EU) 2016/425

In the event of a positive EU type examination of PPE of category III, the applicant (manufacturer / authorised representative / importer / distributor) will be sent a corresponding form by the certification body. The applicant can choose between the following options:

1) Contract for monitoring (supervised product check; Module C2) of the finished PPE in accordance with Regulation (EU) 2016/425 Annex VII
2) Contract for monitoring (quality assurance of the production process; Module D) in accordance with Regulation (EU) 2016/425 Annex VIII

Please note:
In accordance with the provisions of Regulation (EU) 2016/425 the following is required before affixing the conformity marking (CE mark with identification number of the notified body responsible for surveillance) and placing PPE of category III on the market:

1) a positive EU type-examination certificate (module B) must be available and
2) a contract*) for supervised product checks (module C2) with a notified body
   or
3) a contract*) for supervised quality assurance related to the production process (module D) with a notified body.

*) The fulfilment of these requirements / specifications is the responsibility of the manufacturer

4.5. EU type examination

4.5.1. Evaluation

The evaluation[E1) E2) E3)] of the submitted information, technical documents, samples, test reports and evidence is performed by experts from the certification body. The following activities are carried out (see the following sections 4.5.1.1 - 4.5.1.4)

E1) includes checking the available evidence, as well as the technical documentation and the assembly-technical design, checking the submitted test reports, report preparation (see section 4.6. "EU type-examination certificate")

E2) If necessary, explanations of the documents used / consulted for the evaluation (e.g. standards, 'Recommendation for Use (RfUs)', etc.) are provided (on request).

E3) All evaluation activities are carried out by experts from the certification body (in the OETI); outsourcing/subcontracting does not take place under any circumstances. If PPE is used in combination with additional protective equipment (e.g. integrated visors), an "EU type-examination certificate" (from a suitable NB) must be presented/submitted for this protective equipment. (Reference is made to this in the EU type-examination certificate issued by the OETI).

4.5.1.1. Evaluation – harmonised European standards

Checking the available evidence of compliance with the safety-related material requirements (test results) as well as the technical documentation and the technical assembly execution.

Inspecting the test specimen with the information on the technical documentation and the packaging requirements of a harmonised standard is usually carried out as part of the type examination, and if necessary, a separate test order is used.

If the required evidence of material tests is missing, the corresponding evidence (test reports) must be submitted later or tests must be carried out. In order to carry out missing tests, the applicant may instruct the OETI inspection body or another appropriate accredited testing body (see pt. 3.3).

Presumption of conformity
Where harmonised standards or parts thereof are applied, conformity with the essential health and safety requirements in accordance with Regulation (EU) 2016/425 Annex II covered by the relevant standards or parts thereof is presumed on the basis of harmonisation (see "Annex ZA" in the respective standard).

4.5.1.2. Evaluation – non-harmonised European standards (non-harmonised standards/technical specifications/directives)

Checking the available evidence of compliance with the safety-related material requirements (test results) as well as the technical documentation and the technical assembly execution.

If the certification is based on non-harmonised standards, technical specifications and guidelines, the applicant must consider and document:

- the risk mitigated by the PPE and
- what level of protection is achieved.

In assessing this information, the certification body shall use the following documents:

1) PPE Regulation (EU) No 2016/425
2) EN ISO 13688 "Protective clothing — General requirements"
3) Standards with related areas of protection used (if available)
4) If there are no normative principles, the certification is to be carried out in accordance with the requirements of the PPE Regulation (EU) No 2016/425
5) Risk categories of PPE (in accordance with PPE Regulation (EU) No 2016/425, Chapter IV; Article 18 and Annex I)
6) Essential health and safety requirements (in accordance with PPE Regulation (EU) No 2016/425 Annex II)
   For this purpose, the applicant must carry out a risk analysis (e.g. by means of a risk matrix) (this must be submitted together with the technical documentation)

7) In any case, the requirements and the "flowchart for material assessment in protective clothing" according to EN 13688 are adopted

Presumption of conformity

In order to be able to presume conformity with the essential health and safety requirements set out in Regulation (EU) 2016/425 Annex II, when applying non-harmonised standards, the "link between this European Standard and the essential requirements of Regulation (EU) 2016/425 to be covered" shall be established by means of a risk analysis (e.g. by means of a risk matrix) prepared by the applicant.

4.5.1.3. Procedure for deviations

In the event of inadequate documents (technical documentation, user information, labels, etc.), improvements will be requested from the applicant; at the request of the applicant, corrections may be proposed by the certification body. These must be adopted and accepted by the applicant before the applicant uses them or they are included in the certification.

If deviations (*"non-conformities"*) are identified/determined during the "evaluation", the applicant will be actively informed by the certification body (see point 4.5.1.4. "Preliminary report") and asked to provide feedback as to whether there is interest in continuing the certification process. The applicant will also be informed of which additional evaluation tasksEA1) are required to correct the identified/determined deviations (*"non-conformities"*).

If it is determined that one or more requirements are not met and there is an interest in continuing the certification process, the tasks required for improvement/correction must be completed and re-evaluated - as long as the applicant has not made the subsequent submissions or corrections, the certification cannot be completed.

If it is determined that one or more requirements are not met and there is no interest in continuing the certification process and/or there is no possibility of successfully completing the EU type examination through improvement/correction, the issuance of the EU type examination certificate must be refused.
In addition, the matter must be reported to the responsible ministry.

The "evaluation" and the "assessment and certification decision" are carried out by different people, thus ensuring the four-eyes principle.

EA1) Evaluation tasks may include activities such as design review and assessment of documentation, sampling, testing, etc., which may need to be additionally carried out by the certification body.

4.5.1.4. Preliminary Reports

In the course of processing, it may be necessary / desired to send the applicant an overview of the current draft status of the commissioned EU type examination certificate. The form in which this is communicated is the responsibility of the respective employees of the certification body. A possible variant for this is the sending of a "preliminary report", but other notification variants - e.g. as part of a simple e-mail - are also possible

In the event of any deviation(s) ("non-conformities") being identified, the applicant will be informed in writing.

A "preliminary report" is the unfinished "report (EU type examination certificate)" that is currently being processed, which is marked "preliminary report" and converted into a PDF file and sent to the applicant.

The following "colour-coding" is used for the "preliminary report":

Colour-coding	Explanation
red text, without colored underlay and / or red text / yellow underlay	Control for this parameter not (yet) carried out and / or Evidence is (still) missing and / or Explanatory text and / or something still needs to be clarified
red text / yellow underlay and / or red symbol "¥" / yellow underlay and / or (empty yellow field)	
red text / orange underlay and / or red symbol "¥" / orange underlay and / or (empty orange field)	This parameter is already mentioned elsewhere in the document.
black text / light red background and / or black text / red symbol "₡" / light red background	Control for this parameter already performed and requirements not met ("non-conformity")
black text / green background and / or black text / green background	In some cases, it may be useful for individual passed results to be particularly highlighted
blue text (e.g. RGB 0/0/204 or another blue not corresponding to the heading colour)	Will not be visible in the final EU-Type Examination Certificate.
Blue heading, without coloured underlay Black text, without coloured underlay	Control for this parameter performed and passed

Falls If a different colour-coding is used, it will be explained accordingly in the respective preliminary report and/or the associated e-mail.

4.5.2. Assessment and certification decision

After completion of the evaluation, all documents for the evaluation and certification decision are passed on to an evaluator.

The evaluation and certification decision is made simultaneously by the same person who was not involved in the evaluation process.

4.6. Report (EU type examination certificate)

As part of an EU type examination certificate, the results of the determination (evaluation), the evaluation and the certification decision are made out in writing.

Submitted type samples (= samples) are sealed and sent to the applicant together with the EU type examination certificates. The sealed sample/s is/are part of the EU type examination certificate. Documents and sealed samples must be retained by the applicant.

4.7. Declaration of Conformity/EU Declaration of Conformity

After completion, or once an EU type examination has been carried out, a statement of conformity is completed. Based on this, the applicant issues an EU Declaration of Conformity on their own responsibility. The following is an example of an EU Declaration of Conformity to be completed by the customer.

EU-DECLARATION OF CONFORMITY

Object of the declaration is following personal protective equipment (PPE)

product: **jacket**

Manufacturer (*and, where applicable, his authorised representative*)

Manufacturer
Any Company
A-1234 Maxing, Any Street 30

This declaration is issued under the sole responsibility of the manufacturer

The object of the declaration above is in conformity with the relevant Union harmonisation legislation:

Regulation (EU) 2016/425 **personal protective equipment**

Conformity is shown by compliance with the applicable requirements of the following documents

EN ISO 11611:2015	**Protective clothing for use in welding and allied processes**
EN ISO 11612:2015	**Protective clothing - Clothing to protect against heat and flame**
EN ISO 14116:2015	**Protective clothing – Protection against heat and flame – Limited flame spread materials, material assemblies and clothing**

The notified body

OETI - Institut fuer Ökologie, Technik und Innovation GmbH
Siebenhirtenstrasse 12A; Objekt 8; 1230 Vienna, Austria
Kennnummer: 0534

performed the EU type-examination (Module B) and issued the

EU type-examination certificate **VN123 456**

The PPE is subject to the conformity assessment procedure:

Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D) under surveillance of the notified body
OETI - Institut fuer Ökologie, Technik und Innovation GmbH, Kennnummer: 0534

Signed for and on behalf of:	**Any Company**
Place and date of issue:	**Vienna, 31.01.**
Name, function:	**Any Name; function**
Signature:	**……**

Note on signature *(recommendation)*:
The EU DECLARATION OF CONFORMITY should be signed by the commercial managing director or a person authorized by him/her.

4.8. Procedure for non-conformities with the certification requirements

The customer will be informed in writing of any non-conformities found (with regard to certification requirements and product requirements) and requested to rectify them.

4.9. Validity according to Regulation (EU) 2016/425

In accordance with Regulation (EU) 2016/425, the period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed **five years**.

In the event of changes affecting certification a new review of the type examination certificate must be requested. This is true in the following cases:

a) in the event of an amendment to the approved type specimen (e.g. amendment to the approved model, to materials or components or assemblies used)
all modifications to the approved type specimen and all amendments to the technical documentation which may affect the PPE's conformity to the applicable essential health and safety requirements or the conditions for validity of the certificate must be reported, since such modifications require additional approval in the form of an addition to the original EU type examination certificate
or
b) in the event that the state of technology develops
or
c) in the event of changes affecting the applicant (e.g. changes of ownership)
d) at the latest before the validity of the certificate expires
In the case of an application for renewal and if all current requirements at the time of renewal are met, the extended EU type examination certificate is valid for a maximum of 5 years from the date of issue of the initial certification. If an amendment to a reference standard is made prior to the expiry of the 5-year period of validity, the validity remains unchanged, unless the change was made for safety reasons. In this case, the validity ends with the withdrawal of the standard.
At the earliest, an extension of the validity period can be applied for 12 months before the validity is due to expire, but at the latest it must be applied for 6 months before the validity is due to expire

If an application for renewal is submitted only after the validity of the "EU type examination certificate" has expired, a new examination is carried out using a new project number (= number of the "EU type examination certificate").

If an extract of an EU type examination certificate has been drawn up, the validity of the EU type examination certificate remains unaffected and unchanged. The extract does not replace the original EU type examination certificate (unlike in the case of amendment/expansion/extension).

4.10. Using an "EU type examination certificate"and/or conformity marks and advertising materials

By signing the certification agreement (which is attached to the relevant application), the applicant undertakes not to use the product certification in a way that could discredit the certification body and not to make any statements about its product certification that the certification body could consider misleading or unjustified

In case of non-compliance with the above requirements (such as incorrect reference to the certification system and/or misleading use of certificates and/or symbols, etc.), the certification body reserves the right to withdraw the certification after prior written contact and a set deadline for correction.

4.11. Internal production control of the finished PPE in accordance with Regulation 2016/425 Module C

Category II PPE
"Conformity to EU type based on internal production control"

Includes manufacturing and follows Module B.

The manufacturer must carry out an internal production control to ensure the conformity of their product with the EU type approved under Module B.

Before placing the product on the market, before the CE marking may be applied to the PPE, and before an EU DECLARATION OF CONFORMITY may be issued, the manufacturer (contracting entity) must have successfully carried out the internal production control.

4.12. Monitoring completed PPE in accordance with Regulation 2016/425 Module C2

According to Regulation (EU) 2016/425, PPE corresponding to **risk category III** must be subjected to annual monitoring. Before the CE marking can be applied to the PPE, the client must select an institution (notified body = OETI; identification number NB 0534) that will carry out the necessary checks.

Before the conformity marking (= CE mark with identification number of the notified body responsible for monitoring) can be applied to the PPE, the following is required before Category III PPE is attached and placed on the market, in accordance with Regulation (EU) 2016/425):

1) a positive EU type-examination certificate (Module B) must be available and
2) proof of conformity of the respective PPE with the type based on an internal production control*) and
3) a contract*) for a supervised product test (Module C2) with a notified body
   *) Compliance with these requirements / specifications is the responsibility of the manufacturer

Both for EU type examination carried out by the OETI and for EU type examinations not carried out by the OETI, the certification body can be commissioned to monitor the finished PPE (Module C2). In the case of monitoring an EU type examination not carried out by the OETI, the following documents are required (see Regulation (EU) 2016/425 Annex VII, pt. 3):

- the technical documentation referred to in Annex III;
- a copy of the EU type examination certificate.

The following options are available for monitoring of the completed PPE

- Monitoring - on-site (= *presence audit*) ⇨ for details, see point 4.12.1
- Monitoring - using a "remote audit" (= *remote audit*) ⇨ for details, see point 4.12.2

the form of the monitoring-audit is determined by the certification body in consultation with the applicant

The monitoring of the finished PPE (Module C2) or the quality assurance system (Module D) is carried out by an employee of the certification body, this person is hereinafter referred to as "*inspector*"

4.12.1. Monitoring of the finished PPE - on site *(= presence audit)*

The monitoring of the finished PPE on site (= *presence audit*) includes the following:

1) Introduction
   - Welcome / Greeting
   - Start of monitoring
   - Explanation of the process
2) Recording of all valid type specimens and monitoring contracts with the applicant.
3) Verification of the validity of type examination certificates and the underlying harmonised standards, non-harmonised standards, technical specifications, and directives.
   (In the event of changes to the requirements, such as standards or guidelines, the customer will be made aware of this and the resulting consequences for the applicant will be documented in the monitoring report.)
4) Recording of changes (e.g. change of ownership, change of structure)
5) Checking the documentation of customer complaints with the manufacturer
6) Checking the measures from the last monitoring report
7) Assessment of internal production control/internal final control
   a) Checks of internal production control carried out before placing the product on the market and issuing the declaration of conformity (Module C for Category II/Module C2 for Category III)
   b) Assessment of the final internal control with regard to its effectiveness
      It shall be ensured, that the manufacturer takes all necessary measures to ensure that the manufacturing process, including the final inspection of PPE, ensures the homogeneity of production and the conformity of the PPE with the specification/standard described in the EC type examination certificate.
      - Internal specifications
      - Documentation
8) Control / inspection of the warehouse.
9) Random sampling[(A)] checks on PPE with regard to (if necessary):
   - Design
   - Size specifications and labels
   - If applicable, photo documentation of the randomly examined PPE
10) Random sampling[(A)] Monitoring user information (if necessary):
   - User information available?
   - Declaration of Conformity available?
   - Monitoring/inspecting the site.

11) Selection of samples for the verification of the material properties relating to safety
(If the material used is available on site and the relationship between the product and the materials can be traced, the material test can be carried out on goods sold by the metre or their combinations. If the relationship cannot be traced or if there is no material storage on site, completed PPE must be used for laboratory tests.)
12) Conclusion
    - Further procedures (next steps)
    - Résumé

(A) Explanation: The sampling for spot-check inspections is carried out in accordance with the procedure described in ISO 2859-1 [Test level: S-4 (Table 1) and Table 6-C]

Depending on the scope of the EU type examination certificate to be monitored, an on-site inspection is presumed to take at least 2,5 hours.

Reasons for premature termination of an on-site monitoring (= *presence audit*)

The monitoring of the finished PPE on site (= *presence audit*) will be terminated in the following cases

- Access to the place of final product testing and storage is denied
- Taking of samples is denied
- Inspection of documents is denied

In the event that an on-site inspection is prematurely terminated (= audit termination), the costs incurred up to the termination, including the preparation of the audit report, will be invoiced.

In the event that an on-site inspection is prematurely terminated (= audit termination), the validity of the affected "EU type-examination certificates", as described in **pt. 5.2 c)** is immediately suspended.

4.12.2. Monitoring of the finished PPE - by means of "remote audit" *(= remote audit)*

The inspector has the option to carry out site inspections by means of a "remote audit" on a case-by-case basis*).
*) e.g. travel restrictions, time required, repeat audit, etc.

A "remote audit" is an audit that is carried out by people (who are in different physical locations) in an online environment.

In order to be able to monitor the finished PPE by means of a "remote audit", the following prerequisites/requirements must be met:

- *Technical requirements:*
  The remote audit is carried out by means of a video and sound-transmitting meeting (e.g. Microsoft Teams) - mobile image and sound transmission must be possible (this is strictly necessary for the inspection of the site and the collection of the samples!!).
  !! Technical equipment which only enables audio transmission is not sufficient to carry out a remote audit.
  Taking *screenshots* must be permitted.
  The technical capabilities must be checked before the actual date of inspection (a test meeting about 1 week in advance is recommended)
- *Communication requirements:*
  It must be guaranteed that a person is available during the remote audit who can communicate with the inspector (*Language: German or English*)
- *Personnel requirements:*
  The persons (inspector, employees of the company undergoing inspection) should be known in advance.
- *Local requirements:*
  The inspection – those on site by means of "remote audit" take place at the same location as in-person inspections – should take place on site.

- *Documents:*
  Documents which are required for on-site monitoring but which cannot be transmitted visually during the remote audit must be requested in advance and sent if necessary. Which documents are affected can/must be clarified during the trial meeting.
- *Marking of the selected types/samples:*
  In order to clearly identify the samples taken and thus exclude the possibility of swapping items, labels are sent by the certification body to the company undergoing inspection.
  These labels must be affixed to the selected samples during the remote audit or, in the event that the samples are in packaging which cannot be opened without destroying the sample, affixed to the packaging and then signed/initialled by the employee of the company undergoing inspection (the signature/paraphernalia must be done via both the label and the sample)

The procedure described in section 4.12.1. "Monitoring of the finished PPE - on-site (= *presence audit*)" is adapted accordingly to the requirements of a "remote audit" (= *remote audit*).

4.12.3. Monitoring – Properties of the finished PPE (supervised product testing; Module C2)

The monitoring of the properties includes the following:

4.12.3.1. Verification of the ready-to-wear design

For assembled PPE, the essential assembly characteristics as well as the finished dimensions are checked. For this purpose, the ready-to-wear design is checked on the articles randomly selected as part of the on-site inspection (audit). . The manufacturer shall provide

- a sample of the selected articles from production
- as well as the corresponding sealed model

After the assembly check has been carried out, both the sealed model and the sample from production are returned to the manufacturer.

4.12.3.2. Verification of user information and labels

In this case, it is checked whether the user information is enclosed with the extracted PPE sample and whether its content corresponds to that in the technical documentation. Furthermore, the Declaration of Conformity and completeness of the labels are checked.

4.12.3.3. Inspection of safety-related material properties

The aim is to examine all materials used for the production of the certified PPE over an inspection period of 5 years, following the following steps:

- ⇨ an (annual) test plan is drawn up by the OETI
- ⇨ If several articles are made from the same materials or the same material composite, they can be summarised into material groups.
  This ensures that all materials or material composites used for the certified PPE are monitored.
- ⇨ The materials required for the material tests (sold by the meter) are selected during external monitoring (on-site monitoring / monitoring by means of a "remote audit") taken and packaged in the presence of the inspector. The samples are either taken by the inspector or sent to the OETI
- ⇨ The material tests are carried out by the OETI testing department..
- ⇨ Tests are carried out on the material samples to determine their safety properties..

4.12.4. Monitoring report

The certification body issues a "Report on On-Site Monitoring (= *On-Site Audit*) / "Remote Audit" (= *Remote Audit*)" on the "Monitoring of the finished PPE - on-site (= *presence audit*)" / "Monitoring of the finished PPE - by means of a "remote audit" (= *remote audit*)" carried out. In addition, a report on the tests carried out to monitor the properties and a **monitoring report** are issued.

Any causes and reasons for restriction, suspension or withdrawal due to identified deviations are stated in the monitoring report (see Section 5)

4.13. Monitoring of quality assurance related to the production process in accordance with Regulation 2016/425, Annex VIII (Module D)

According to Regulation (EU) 2016/425, the quality assurance system of the manufacturer of PPE corresponding to risk category III must be subject to annual surveillance.

Prior to the application of the conformity marking (= CE mark with identification number of the notified body responsible for monitoring) on the PPE, the following is required for category III PPE:

1) a positive EU type-examination certificate (Module B) must be available and
2) a contract*) for monitoring (monitored quality assurance related to the production process; Module D) according to Regulation (EU) 2016/425 Annex VIII with a notified body

*) Compliance with these requirements / specifications is the responsibility of the manufacturer

For both EU type examinations carried out by the OETI and EU type examinations not carried out by the OETI, the certification body can be commissioned to monitor the finished PPE (Module D). In the case of monitoring an EU type examination not carried out by the OETI, the following documents are required (see Regulation (EU) 2016/425 Annex VIII point 3):

- the technical documentation in accordance with Annex III;
- a copy of the EU type examination certificate.
- Documents on the quality assurance system in accordance with Regulation (EU) 2016/425 Annex VIII point 3.2

The following options are available for monitoring of the completed PPE

- Monitoring - on-site (= *presence audit*) ⇨ for details, see point 4.13.1
- Monitoring - using a "remote audit" (= *remote audit*) ⇨ for details, see point 4.13.2

the form of the monitoring-audit is determined by the certification body in consultation with the applicant

The quality assurance system is monitored by an employee of the certification body, this person is hereinafter referred to as "inspector"

4.13.1. Monitoring of the quality assurance system - on-site (= *presence audit*)

On-site monitoring (= *presence audit*) includes the following:

1) Introduction
   - Welcome / Greeting
   - Start of monitoring
   - Explanation of the procedure / process
2) Recording of all valid type specimens and monitoring contracts with the applicant.
3) Verification of the validity of the type-examination certificates and the underlying harmonised standards, non-harmonised standards, technical specifications, and directives / guidelines. *(In the event of changes to the requirements, such as standards or guidelines, the customer will be made aware of this and the resulting consequences for the applicant will be documented in the monitoring report)*
4) Recording of changes (e.g. change of ownership, change of structure)
5) Checking the documentation of customer complaints with the manufacturer
6) Checking the measures from the last monitoring report
7) Examination of the quality assurance system documents
   - All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.
   - The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.
   - The quality system documentation shall, in particular, contain an adequate description:
     a) the quality objectives and the organisational 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

8) Control / inspection of the warehouse
9) Random sampling[A] checks on PPE with regard to (if necessary)
   - Design
   - Size specifications and labels
   - If applicable, photo documentation of the randomly examined PPE
10) Random sampling[A] of the user information (if necessary):
   - User information available?
   - Declaration of Conformity available?

[A] Explanation: Sampling for random control is carried out according to the procedure described in ISO 2859-1 [test level: S-4 (Table 1) and Table 6-C

11) Selection of samples for the verification of the material properties relating to safety (if necessary) *(The inspector has the right to take samples for checking the safety-related material properties (e.g. in the event that the documents submitted do not contain any comprehensible evidence of the examinations and tests carried out.))*
12) Conclusion
   - Discussion of deviations / non-conformities, measures, definition of deadlines, further procedure (next steps)
   - Signature by the customer of the list of corrective measures adopted
   - Résumé

Depending on the scope of the EU type-examination certificate / quality assurance system to be monitored, a duration of at least 5 hours is assumed for an on-site monitoring (= *presence audit*)

Reasons for premature termination of an on-site monitoring (= *presence audit*)

The on-site monitoring (= *presence audit*) will be terminated in the following cases

- Access to the place of final product testing and storage is denied
- Taking of samples is denied
- Inspection of documents is denied

In the event that an on-site inspection is prematurely terminated (= audit termination), the costs incurred up to the termination, including the preparation of the audit report, will be invoiced.

In the event that an on-site inspection is prematurely terminated (= audit termination), the validity of the affected "EU type-examination certificates", as described in **pt. 5.2 c)** is immediately suspended.

4.13.2. Monitoring of quality assurance - by means of "remote audit" *(= remote audit)*

The inspector has the option to carry out site inspections by means of a "remote audit" on a case-by-case basis*).
*) e.g. travel restrictions, time required, repeat audit, etc.

A "remote audit" is an audit that is carried out by people (who are in different physical locations) in an online environment.

In order to be able to carry out a "remote audit" of the quality assurance system, the same prerequisites / requirements as in point 4.12.2. (= Monitoring of the finished PPE - by means of "remote audit" (= remote audit)) must be met:

- *Technical requirements*
- *Communication requirements*
- *Personnel requirements*
- *Local requirements*
- *Documents*
- *Marking of the selected types/samples*

The procedure described in section 4.13.1. "Monitoring of the quality assurance system - on-site (= *presence audit*)" is adapted accordingly to the requirements of a "remote audit" (= *remote audit*).

4.13.3. Monitoring – Properties of the finished PPE (if required as part of quality assurance monitoring; Module D)

If it is necessary to take samples [see explanations in section 4.13.1, point 11)], proceed as described in section "4.12.3. Monitoring - Properties of the finished PPE (supervised product testing; Module C2)".

4.13.4. Monitoring report

The certification body issues a "Report on On-Site Monitoring (= *On-Site Audit*) / "Remote Audit" (= *Remote Audit*)" on the "Monitoring of the quality assurance system - on-site (= *presence audit*)" / "Monitoring of the quality assurance system - by means of a "remote audit" (= *remote audit*)" carried out. To determine whether the required requirements are met, an assessment of the quality assurance system is carried out based on the findings of the audit (on-site audit or remote audit).In any case, a monitoring report will be issued

If, as part of the audit (on-site audit or remote audit), it is necessary to take a sample to check the safety-related material properties, the reports are issued in the same way as for Module C2.

Any causes and reasons for restriction, suspension or withdrawal due to detected deviations are stated in the monitoring report (see section 5)

5. Termination, restriction, suspension, or withdrawal

5.1. Termination

A certification can be terminated at any time at the client's request. For this purpose, a written notification is required. Upon completion, one of the following forms (with 2 copies) will be sent to the customer. These must be signed and one of the two signed forms must be returned to the certification body (NB 0534), the second remains with the customer:

- **Category II** PPE: "Termination of Production/Manufacturing (Category II)"
- **Category III** PPE: "Termination of production/manufacturing and the contract for the inspection of the finished PPE (Category III)"

If no extension is requested before the validity period expires, the validity expires automatically. No written consent from the customer is required.

Insolvency (bankruptcy) of the contractor will result in the immediate termination of the validity of all affected certifications (= *EU type examination certificate*).

In the event of termination, the following must be observed (notes):

- *the PPE in question may no longer be produced and placed on the market from that date.*
- *In accordance with PPE Regulation (EU) 2016/425, the notified verifier shall keep all relevant documents and samples for at least five years after that date and then dispose of them.*

- *Documents (the EU type examination certificate together with annexes, additions, and with the technical documentation) and specimens kept by the manufacturer/distributor may be disposed of ten years after the date of termination*

5.2. Restriction, suspension, or withdrawal

Suspension at the client's request

Certification can be suspended at the client's request. For this purpose, a written notification is required.

In the event of suspension, the following are to be observed:

- A suspension at the customer's request is possible for a maximum of 5 years.
- No affected PPE may be produced and placed on the market for the duration of the suspension
- Prior to resuming new production and market placement, the certification body must carry out a verification

Restriction, suspension or withdrawal due to detected deviations

In the event that deviations are detected (non-compliance with certification requirements) in the course of monitoring or otherwise , a restriction, suspension, or withdrawal of the certification may be carried out.

If, during the annual inspection or by any other means, a deviation/non-conformity with certification requirements is detected, the following measures are applied depending on the deviation detected:

Deviation/non-conformity in the course of annual monitoring

a) *Continuation of certification under conditions*.
The conditions for continuation are determined by the certification body (e.g. enhanced surveillance) ; The client will be informed of this in writing, as well as of the necessary steps to regain the full scope of certification (e.g. in the inspection report section "Measures and consequences for the applicant").

b) *Limitation of scope*
In this case, all non-compliant products will be removed from the corresponding "EU type examination certificate(s)". To this end, the "EU type examination certificate(s)" concerned shall be amended
The client will be informed of this in writing, as well as of the necessary steps to regain the full scope of certification (e.g. in the inspection report section "Measures and consequences for the applicant")

c) *Suspension of the EU type examination certificate*
In the event of a suspension, the validity of the affected "EU type examination certificate(s)" shall be suspended. The duration of the suspension may be set until the end of the validity period at most. The contracting entity shall be informed of this in writing, as well as of the measures to be taken to terminate the suspension and restore the certification (e.g. in the inspection report section "Measures and consequences for the applicant").

d) *Withdrawal of certification* (Revocation of certification).
In the event that the PPE or an EU type examination certificate has been used whilst restrictions or suspensions are in place, the EU type examination certificate shall be withdrawn immediately. The contracting entity shall be informed of this in writing, and the notifying authority shall likewise be informed in writing.

The following must be observed (notes):

- *No affected PPE may be produced and placed on the market for the duration of the suspension*
- *If safety-related **insignificant/minor deviations** (e.g. in the layout) are detected, this will be pointed out in the inspection report and appropriate improvement measures will be required.*
- *In the case of **basic safety-related deviations** (e.g. target value has not been reached), a negative inspection report is issued with a reference to the deviations.*
- *If **corrective actions are possible,** the certification body will set a deadline (the client must implement and prove appropriate corrective measures within a **period of three months)** for their implementation. Once the corrective measures have been taken, they will be checked and a new inspection report will be issued.*

- *If **corrective measures are not possible,** a report is sent to the responsible Federal Ministry, in addition to the negative monitoring report.*
- *If the client does not comply with this request, or if the requirements are not met despite corrective measures, all affected*"EU type examination certificates" will be withdrawn and the corresponding notifying body/Federal Ministry will be notified.
- *In the event of fundamental safety-related deviations that cannot be corrected, the applicant must dispose of the stock. In this case, the monitoring body (notified body) reserves the right to impose a "product recall" on the manufacturer for the affected PPE that has already been delivered*
- *If rework is possible and PPE in stock can be corrected/repaired, then this must be done prior to sale.*
- *If reworking is possible during production, but PPE already in stock cannot be corrected/repaired, the stock must be disposed of.*

*Deviation/non-conformity **not** in the course of annual inspections*

In the event that it is otherwise indicated that the PPE does not conform to the type described in the EU type examination certificate, the following steps shall be carried out by the certification body (= notified body).

- Request all documents which prove the deviations
- Ensure the clear assignment to the EU type examination certificate issued by the certification body
- Verification of the indicated/detected defects
- Depending on the indicated and detected deficiency, the measures described above [pts. a) to c)] are then carried out, with the relevant notes taken into account
- If the reported/detected defects pose a risk to the health or safety of individuals, the EU type examination certificate shall be withdrawn immediately. The contracting entity shall be informed of this in writing, and the notifying authority shall also be informed of this in writing.

Terminating the certification at the client's request

At the written request of the client, the certification can be terminated (see pt. 5.1)

5.3. Obligations of the applicant in the event of the termination, restriction, suspension, or withdrawal of certification

By signing the corresponding application form, the applicant undertakes to take the following measures in the event of suspension, withdrawal, or termination of certification:

1) stop using any promotional materials containing any reference to certification
2) and return all documents required by the certification body
3) and take all other necessary measures to ensure that no further sale is made with reference to the certification.

Annex A – Products and standards included in the certification programme

Products

The following products/product groups are included in the "Certification Programme (Product Certification Programme) for Personal Protective Equipment (PPE)":

Protective clothing

- Hand and arm protection
- Feet and leg protection
- General body protection (clothing)
- Respiratory protection
- Mechanical risks
- Heat, [Heat <100°C / >100°C and fire]
- Cold [Cold >-50°C / Extreme cold <-50°C]
- Electrical risks
- Chemical Agents
- Biological Agents
- High visibility clothing
- Protective clothing for motorcycle riders
- Firemen suits
- Protective clothing against hand-held chain-saws
- Protection against knife cut

Standards

The requirements according to which the products are evaluated are based on harmonised standards, non-harmonised standards, technical specifications, and guidelines. If necessary, the standard requirements can be specified and made available in more detail (on request).

An overview of all standards for which an EU type examination can be carried out by the certification body of the OETI (identification number NB 0534) will be provided on request.

All other requirements not contained in the relevant requirements standards that must be met are contained in Regulation (EU) 2016/425. An overview of this and further information required for certification can be found in the overview in Annex B.

Annex B – Overview of "required information"

In order to carry out a type examination and the subsequent issue of a type examination certificate, the following information must be provided to the OETI by the applicant (manufacturer/authorised representative/importer/dealer).

- Name of manufacturer/authorised representative/importer/distributor
- Description of the personal protective equipment (PPE)
- Harmonised standards, non-harmonised standards, technical specifications, and directives applied
- Citations of harmonised and non-harmonised standards, technical specifications and directives
- Risk assessments (assessment of the risks protected against by PPE)
- Essential health and safety requirements
  - Applicable essential health and safety requirements
  - Results of studies to verify that the PPE conforms to the applicable essential health and safety requirements
  - Risk assessment to identify the risks associated with the PPE
- Information on all materials used
- Description of the PPE (ready-to-wear version) and its intended use
  - Description of the ready-to-wear product
  - Intended use
- Instructions for the production of custom-made PPE (if necessary)
- Instructions for assembly and manufacturing processes of mass-produced PPE and PPE individually adapted to the user (if necessary)
- Sketches (design and production drawings of the PPE)
- Ready-made sizes and finished dimensions
- Label design
- Description of the final internal inspection
- Test reports of material tests
- User information (instructions and information from the manufacturer)
- EU Declaration of Conformity (previously Declaration of Conformity)

Details can be provided in the "TECHNICAL DOCUMENTATION FOR PPE" template. We are happy to provide these upon request.

Annex C – Certification process

	Activity	Executed by Customer	Certification body
I	Selection *(Actions to obtain all the information required for the subsequent investigation)*	a. Inquiry	⇨ Application/request evaluation ⇨ Answer the inquiry ⇨ Make an offer
		b. Send the application for certification alongside all necessary documents and samples to the OETI *(see pts. 4.4.1/4.4.2)*	⇨ Application/request evaluation *(if not already completed)* ⇨ Check whether all required documents and models are available
II	Investigation *(Actions to obtain information regarding product requirements as a basis for evaluation and confirmation)*		⇨ Evaluation of the submitted documents and samples regarding their conformity to the applicable requirements ⇨ The customer will be informed immediately of any non-conformities that may exist
III	Assessment *(Verification of suitability with a view to meeting specified requirements)*		⇨ Verification of the proof of conformity obtained during the "investigation" in order to determine whether the specified requirements are met
IV	Decision *(Decision on certification on the basis of information from pts. II and III)*		⇨ Decision on certification *(grant, maintain, extend, restrict, suspend, withdraw)*
			⇨ The certification decision is made by an employee who was not involved in the evaluation process
V	Confirmation *(Issuing a statement of conformity based on the previous steps)*		⇨ Issuance of the following documents ○ Type examination certificate ○ Appendix to the type examination certificate ○ Certificate for EU type examination certificate" ○ Inspection contract (for Cat. (III)
			⇨ Identification of certified models by attaching a sealed label (with stated type number)
			⇨ Send the documents and sealed samples to the customer
VI	Monitoring *(systematic review of conformity assessment activities to maintain the validity of the conformity statement)*	Relevant for Category III PPE a. Commissioning the monitoring of the end product by signing the monitoring contract	⇨ Preparation and implementation of monitoring ⇨ For details see pt. 4.12/4.13

Annex D – Terms

Confirmation
Produce a conformity statement based on the post-assessment decision that compliance with the specified requirements has been demonstrated.
(see EN ISO/IEC 17000:2004 pt. 5.2)

Conformity statement
The resulting statement, referred to by this International Standard as a conformity statement, provides assurance that the specified requirements have been met. Such confirmation is not in itself a contractual, statutory, or any other guarantee.
(see ISO/IEC 17000:2004, 2.1)

Conformity assessment
Demonstrate that specified requirements relating to a product, process, system, person, or entity are met.
(see ISO/IEC 17000:2004, 5.2, Note 1)

Programme owner
The person or organisation responsible for developing and maintaining a particular certification programme.

Certification
Confirmation by a third party related to products, processes, systems or persons
(see EN ISO/IEC 17000:2004 pt. 5.5)

The certification of products, processes, or services provides a means of ensuring that they meet specified requirements in standards and other normative documents.

Certification Programme
A certification system referring to specific products to which the same defined requirements, specific rules and procedures are applied.

The rules, procedures, management, and control of the certification of products, processes and services are determined by the certification programme.

Certification system
Rules, procedures, and management for the awarding of certifications
NOTE: A "certification system" is a "conformity assessment system", which is defined in ISO/IEC 17000:2004, Definition 2.7. (= "Conformity assessment system: rules, procedures and management for the execution of conformity assessments")

About us - Certification body

Spanning decades, our core competence lies in the testing of textiles and garments, as well as the certification of personal protective equipment (PPE).

In our "personal protective equipment department" the OETI (NB 0534) certifies your PPE to obtain the CE marking. Personal protective equipment refers to all garments that are intended to protect persons from dangers to life or health. Protective clothing in this sense includes equipment against special high risks (e.g. chemical protective clothing), other protective clothing such as garden gloves, rain and cold protection, as well as protective clothing for road workers – such as high-visibility vests.

Your contact partners

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If you have any questions or would like to make an offer, please do not hesitate to contact us.

Our mission

We deliver reliable, high-quality consulting, testing and certification services worldwide.

We are independent, highly-skilled and customer-oriented.

With our specialist teams, we offer comprehensive service and safety in the areas of ecology, textiles, flooring technology and interior design.

We increase our customers' competitiveness.

We act responsibly towards our employees, our customers and our environment.

Competence creates confidence