



To  
OETI - Institut fuer Oekologie, Technik und Innovation GmbH  
Notified Body No. NB 0534  
Siebenhirtenstrasse 12A, Objekt 8  
1230 Wien  
AUSTRIA

**Application for issuing a prolongation of validity of EU type-examination certificate no: ..... for personal protective equipment (PPE) applying a simplified review procedure**

Applicant: .....  
*(tick the appropriate)*       manufacturer /  authorised representative /  importer /  distributor

Authorised signatory: .....

Person in charge: .....

Address (street): .....

Postal code, place, country: .....

Telephone / fax / email: .....

**We herewith submit this application only to this accredited certifying body for a prolongation of the EU type-examination certificate pursuant according to Regulation (EU) 2016/425 of the European Parliament and of the Council, for the following PPE:**

*Designation allowing a clear identification of the product within the applicant's company and to be shown both on the product (label) as well as in the technical file (name or item number). For multi-part outfits please provide separately by garment (e.g.: jacket and trousers)*

**Standards and guidelines applied in the manufacturing of the PPE:**

- Regulation (EU) 2016/425 of the European Parliament and of the Council
- EN ..... • ..... • .....
- ..... • ..... • .....

**Manufacturing company**  
(if different to initial application):

**Manufactured in**  
(if different to initial application):

The following shall be enclosed with the application:

- the current technical documentation according Regulation (EU) 2016/425 Annex III
- sealed sample of the PPE from the current type certificate
- one current production sample of the PPE
- for category III products the results of the supervised product checks (Monitoring Reports)

## Confirmation

The applicant confirms by signing the "Application for issuing a prolongation of validity applying a simplified review procedure", that there has been no modification to the above mentioned and approved type-sample regarding neither

- the included materials, sub-components or sub-assemblies,
- nor the technical documentation
- nor the harmonised standards or other technical specifications applied,

that may affect the conformity of the PPE with the applicable essential health and safety requirements or the validity conditions of the certificate.

The applicant further confirms that it is ensured that the PPE continues to meet the applicable essential health and safety requirements according to the state of the art.

*The certification body (notified body) reserves the right, if necessary also within the framework of a simplified review procedure, to check the submitted documents and samples and, if necessary, to demand material tests*

### **A) Simplified review procedure (= procedure in case of no changes)**

- A1) *A simplified review procedure is carried out based on the applicant's confirmation that no changes have been made to the materials, components, assemblies and technical documentation used. The correctness of this information is the sole responsibility of the applicant.*
- A2) *In any case, the actuality of the applied harmonised standards, norms or technical specifications is checked (by the certification body). If an update is found here, the simplified review procedure cannot be applied and the procedure described in point B) is carried out.*
- A3) *If, in the course of the inspection of the submitted documents and/or samples and/or required material tests, it is found that deviations exist, the simplified review procedure cannot be applied and the procedure described in point B) is carried out.*
- A4) *After positive verification of points A2) & A3), the EU type examination certificate is renewed (= extension of validity).*

### **B) Procedure to be followed in the event of any changes found**

- B1) *The present application is considered as an "application for the extension of the validity of the type examination certificate" (without application of the simplified review procedure).*
- B2) *The necessary tests are carried out to ensure that the approved type continues to meet the applicable essential health and safety requirements.*
- B3) *After positive verification of points B1) & B2) the EU-type examination certificate is renewed (= extension of validity).*



## Certification agreement

The following certification agreement corresponds to the requirements according EN ISO/IEC 17065:2013.

- a) The applicant is aware that an application for a type-examination certificate for a PPE can only be submitted in one location and that a decline by this body is reported to the supervising authorities.
- b) The applicant is aware that the certification requirements including implementing appropriate changes when they are communicated by the certification body must always fulfil
- c) The applicant is aware that if the certification applies to ongoing production, the certified product continues to fulfil the product requirements (see EN ISO/IEC 17065:2012 Pkt. 3.8);
- d) The applicant is committed to make all necessary arrangements for
  1. the conduct of the evaluation (see 3.3) and surveillance (if required), including Provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors;
  2. investigation of complaints;
  3. the participation of observers, if applicable;
- e) The applicant committed that all claims / statements regarding certification consistent with the scope of certification
- f) The applicant committed that he does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any Statement regarding its product certification that the certification body may consider misleading or unauthorized;
- g) The applicant undertakes in suspension, withdrawal or termination of the certification to take following by the certification program required measures:
  1. to stop the use of all advertising materials which contain any reference to the certification
  2. and shall return all documents requested by the certifying body
  3. and also take care that all other necessary arrangements were realised that no further sales with respect to the certification takes place
- h) The applicant committed that if he provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme
- i) The applicant committed that in making reference to its product certification in communication media (eg. documents, brochures or advertising materials) no type-examination certificate or any part thereof will be used in a misleading way
- j) The applicant complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product;
- k) The applicant complies to keep a record of all complaints made known to it relating to compliance with certification of requirements and makes these records available to the certification body when requested, and
  1. takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;
  2. documents the actions taken;
- l) The applicant complies with the commitment to inform the certification body, without delay, of changes that may affect its ability to conform with the certification requirements
- m) The manufacturer declares that the examination reports submitted refer to the materials used for manufacturing PPE.

**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
- n) The applicant shall provide the certifying body with the required number of PPE models in the required sizes.

- o) The applicant shall provide sufficient samples of the materials used for necessary laboratory examinations.
- p) The applicant agrees that examinations may also be passed on to other accredited certifying bodies.
- q) The applicant declares that it is not aware of any detrimental health effects of the materials used in the PPE.

Declaration on harmful substances

As a manufacturer and/or person who puts the product on the market I know

- that the a.m. article shall not contain any health impairing concentrations of substances according to annex XIV and XVII of Regulation (EC) No. 1907/2006 (REACH), Regulation (EU) No. 528/2012 (Biocide-Regulation) and Regulation (EC) No. 850/2004 (POP-Regulation).
- that the requirement for PAH (polyaromatic hydrocarbons) in articles to AfPS GS 2019:01 and for PCP according to the German Chemicals Prohibition Ordinance must be fulfilled.
- that materials for PPE should not affect the health or hygiene of the user.
- that materials do not release substances generally known to be toxic, carcinogenic, mutagenic, allergenic, toxic to reproduction or otherwise harmful under foreseeable conditions and under normal use.

- r) The precise rates for the type-examination are known and accepted.
- s) Changes affecting certification
1. The applicant is committed to inform the notified body of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate.
  2. The applicant commits to inform the notified body of any changes concerning the client (for example, ownership changes)
- t) Confidentiality: The certification body commits itself that all information which are obtained or created during the certification activities will be considered as confidential (in accordance with the confidentiality agreement, according to the terms and conditions of our general business terms). Without a prior approval by the customer no content will be made publicly available by the certification body.  
Excluded are all informations that are made available to the public by the customer itself, or when there is an agreement for publication between the client and the certification body.
- u) Information about certified products: The certification body is obliged to record information about the certified products (archiving). On request, the certification body must inform at least about the validity of a particular certification. In addition to the purposes of confidentiality [see pt. "Confidentiality"], without previous approval by the customer, no information about the content of the type-examination certificate as well as all documents and samples related will be passed on.
- v) The certification of personal protective equipment (PPE) is based on the valid certification program (product certification program). The certification program is available on request at any time.
- w) In the event that the processing/completion of the commissioned EU type-examination certificate is refused by the customer (e.g. no response from the customer despite multiple queries from OETI), OETI reserves the right to stop further activities at the commissioned EU type-examination certificate. In this case, a corresponding report and an invoice for the expenses already incurred will be issued, and the responsible authorities will be informed. Placing the affected article on the market is not permitted.

.....  
Place and date

.....  
Applicant's signature