An
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 an EU type-examination for personal protective equipment (PPE) in accordance with Regulation (EU) 2016/425

Details to the Applicant

Applicant: .....

(tick the appropriate) ☐ manufacturer ☐ authorised representative ☐ importer / ☐ listributor

Authorised signatory: .....

Person in charge: .....

Address (street): .....

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

Telephone / fax / email: .....

Number of the EU type-examination certificate concerned *(please complete)*

.....

Type of application *(tick the appropriate)*

☐ **Application is hereby made to this accredited certification body for the prolongation of the validity of the aforementioned EU type-examination certificate (Module B) in accordance with Regulation (EU) 2016/425 of the European Parliament and of the Council**

☐ **Application is hereby made to this accredited certification body for a simplified review procedure for the prolongation of the validity of the aforementioned EU type-examination certificate (Module B) in accordance with Regulation (EU) 2016/425 of the European Parliament and of the Council**

Confirmation

The applicant confirms by signing of "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 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.

Furthermore, the applicant guarantees, that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.

The applicant agrees, accepting the terms of the procedures described below, that the certification body (notified body) controls the submitted documents and samples in order to carry out a simplified verification procedure.

Procedure for no changes

- *If it is found that **no modification** has been made to the approved type, or to the current technical documentation, or there has been no change in the state of the art, the **simplified review procedure** will be applied and*
- *the EU type-examination certificate will be renewed (=prolongation of validity)*

Procedure for changes

- *If the certification body (notified body) determines, that there has been a **modification** to the approved type and / or to the current technical documentation and / or there have been changes in the state of the art, **no simplified verification procedure** can be applied*
- *In this case*
  - *the applicant will be informed promptly of the facts and the present application will be considered as an application for the extension of validity of the type examination certificate (without the application of the simplified review procedure)*
  - *the necessary tests will be carried out to ensure that the approved type continues to fulfil the applicable essential health and safety requirements*
- *after completion of the necessary tests the EU type-examination will be renewed (=prolongation of validity)*

Details of the personal protective equipment submitted

Designation that allows clear allocation to the product within the applicant's company and that is included both on the product (label) and in the user information and technical documentation (name or article number). In the case of multi-part clothing, separately for each item of clothing (e.g. jacket and trousers)

Product description: .....

Article number: .....

General area of use: .....

☐ No changes to the "*Details of the personal protective equipment submitted*"
(tick if applicable)

Standards and directives taken into account in the manufacture of the PPE:

☐ **unchanged scope of standards and directives** taken into account for the previous (previously mentioned) EU type-examination certificate (Module B) in accordance with Regulation (EU) 2016/425, if necessary adaptation to the applicable / valid versions of the applied standards and directives

☐ **Changed scope of standards and directives** taken into account for the previous (previously mentioned) EU type-examination certificate (Module B) in accordance with Regulation (EU) 2016/425, if necessary adaptation to the applicable / valid versions of the applied standards and directives
(ATTENTION: in this case, it is not possible to carry out a simplified verification procedure)

- .....
- .....
- .....
- .....
- .....
- .....
- .....
- .....
- .....

Details of the place of manufacture of the personal protective equipment

Manufacturer Company *(if different from applicant)*	**Place of manufacturing** *(if different from applicant)*

The following shall be enclosed with the application:

- the current technical documentation according Regulation (EU) 2016/425 Annex III including information about all changes
  - by the included materials, sub-components or sub-assemblies,
  - within the technical documentation
  - the harmonised standards or other technical specifications applied,
  - on the PPE
- sealed sample of the PPE from the current type-examination certificate
- one current production sample of the PPE
- for category III products the results of the supervised product checks (Monitoring Reports)

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 fulfils

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 required);

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. In the event of non-compliance (e.g. incorrect reference to the certification system and/or misleading use of certificates and/or marks, etc.), the certification body reserves the right to withdraw certification after prior written contact and a deadline set for rectification.

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 promotional materials which contain any reference to the certification
   2. and shall return all documents requested by the certifying body
   3. if necessary, implement the measures imposed on the PPE produced / stored / delivered (for details see certification program; section 5.2)
   4. 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 (e.g. 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 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.

x) Validity: In accordance with Regulation (EU) 2016/425, the period of validity of a newly issued EU type-examination certificate and, in the case of an extension of the validity of an EU type-examination certificate, may not exceed five years; however, the certification body reserves the right to determine the period of validity on a case-by-case basis. If no extension is requested before the expiry date, the validity expires automatically; no separate consent from the customer is required for this.

y) **Important information on Category III:** 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 monitoring) and placing Category III PPE on the market:
   1. a positive EU type-examination certificate (module B) must be available and
   2. a contract for supervised product testing (Module C2) with a notified body or
   3. a contract for supervised quality assurance in relation to the production process (Module D) with a notified body

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

The undersigned certifies that the application form (for the PPE model(s) described and submitted above) has been completed truthfully and agrees to the Certification Agreement.

.....	.....
Place and Date	Signature of an authorized employee with the applicant's company stamp