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



Application for the issue of an EU type-examination certificate for personal protective equipment (PPE)

Details to the Applicant

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

Authorised signatory:

Person in charge:

Address (street):

Postal code, place, country:

Telephone / fax / email:

Type of application (tick the appropriate)

- ☐ New EU-type-examination certificate (**Initial certification**)
Application is hereby made for the first time and only to this accredited certification body for the issue of an EU type-examination certificate (Module B) in accordance with Regulation (EU) 2016/425 of the European Parliament and of the Council
- ☐ **Modification / Amendment** to the EU type-examination certificate:
Application is hereby made to this accredited certification body for the amendment/addition of the aforementioned EU type-examination certificate (Module B) in accordance with Regulation (EU) 2016/425 of the European Parliament and of the Council

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 for "Commissioning of a Modification / Amendment")

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

- ☐ EN ISO 13688 (in the current version) Protective clothing — General requirements
- ☐ EN ISO 21420 (in the current version) Protective gloves — General requirements and test methods
- (tick the appropriate)

Insert other applicable standards and directives below

(if required / applicable - with details of the desired / targeted performance levels / classes / types)

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When commissioning an Modification / Amendment to an existing EU type-examination certificate

Amendment(s) / addition(s) to be made to the original type-examination certificate (e.g. additional outer material, etc.)

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Details of the place of manufacture of the personal protective equipment

Manufacturer Company (if different from applicant)

Place of manufacturing (if different from applicant)

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The following shall be enclosed with the application:

- the at least one complete set of personal protective equipment (PPE);
in any case when commissioning a new EU type-examination certificate (initial certification)
- the technical documentation in accordance with Annex III of Regulation (EU) 2016/425

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 be fulfilled
- 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 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.
- 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