Technical info sheet
CE marking protective clothing

CE marking requirements

According to Regulation (EU) 2016/425 for personal protective equipment (PPE) clothing protecting people against threats to life or health must carry a CE mark and fulfil specific requirements.

With personal protective equipment (PPE) is meant, equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety . PPE shall classified in accordance to the risk categories set out in Regulation (EU) 2016/425 Annex I.

Different classes

The regulation (EU) 2016/425 (Annex I) defines three classes of PPE:

- Category I PPE - includes exclusively the following minimal risks.
  - superficial mechanical injury;
  - contact with cleaning materials of weak action or prolonged contact with water;
  - contact with hot surfaces not exceeding 50 °C;
  - damage to the eyes due to exposure to sunlight (other than during observation of the sun);
  - atmospheric conditions that are not of an extreme nature.

- Category II PPE - includes risks other than those listed in Categories I and III.

- Category III PPE - includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following.
  - substances and mixtures which are hazardous to health;
  - atmospheres with oxygen deficiency;
  - harmful biological agents;
  - ionising radiation;
  - high-temperature environments the effects of which are comparable to those of an air temperature
    of at least 100 °C;
    - low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less;
  - falling from a height;
  - electric shock and live working;
  - drowning;
  - cuts by hand-held chainsaws;
  - high-pressure jets;
  - bullet wounds or knife stabs;
  - harmful noise.

OETI - Institut fuer Oekologie, Technik und Innovation GmbH | Siebenhirtenstrasse 12A, Objekt 8
1230 Vienna, Austria
tel +43 1 5442543-0 | email office@oeti.biz | FN 326826 b | VAT No. ATU65149029
www.oeti.biz

Member of TESTEX Group

Conformity procedures

Before placing on the market, the personal protective equipment must be fulfill the following requirements:	category I	category II	category III
technical documentation	required	required	required
essential health and safety requirements	required	required	required
Risk assessment NEW	required	required	required
Type-examination issued by a notified body [module C *)]		required	required
declaration of conformity	required	required	required
CE marking	required	required	required
internal production control	required NEW	required NEW	
internal production control plus supervised product checks [module C2 *)]			required

*) according to Regulation (EU) 2016/425

Type-examination by a notified body (Modul C)

OETI - Institut fuer Oekologie, Technik und Innovation GmbH was approved and notified by the Commission of the European Union (ID number 0534). As a notified body we conduct type-examinations as well as quality assurance for the final protective clothing product. Type-eximations issued by us are recognized Europe-wide.

Quality Assurance of the final product - Conformity to type based on internal production control plus supervised product checks (Modul C2)

Based on Regulation 2016/425 (Module C2) a quality assurance system established by the PPE manufacturer must be monitored regularly in the form of an audit by a body appointed by the European Commission. It must be assured that the PSA-model fulfills fundamental saftey requirements and matches the approved type. Required inspections are carried out randomly once a year.

The monitoring process involves:

- On-site inspections in order to:
  - check all valid monitoring contracts & validity of type approval certificates
  - check and record changes/ check reclamation documentation
  - assessment of the effectivness of the manufacturer‘s end control
  - randomly check product samples, user information and stock
  - selection of material samples for lab testing
- Monitoring of the execution of the finished product and safety of material properties

Confidentiality (secrecy) and information on certified products

The certification body is committed to the confidentiality of all data, results and information obtained or created during the realisation of the certification activities. For the purposes of confidentiality (secrecy) to certified products no information will be passed on. Only on request an information about the validity of a certain certification will given.

Please contact our team for a more detailed information (concerning the requirement for a certification, the necessary documentation or the certification schemes) or a quote:

Judith Pointner | email judith.pointner@oeti.biz | tel +43 1 5442543 28 | mobile +43 699 16060828
Marion Pfeiler | email marion.pfeiler@oeti.biz | tel +43 1 5442543 56 | mobile +43 699 16060856

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