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.

The CE mark indicates that the PPE conforms to the essential health and safety requirements set out in the EU directives.

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.
**Conformity procedures**

Before placing on the market, the personal protective equipment must be fulfill the following requirements:

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<th>Category</th>
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<td>Essential health and safety requirements</td>
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<td>Type-examination issued by a notified body [module C *])</td>
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*) according to Regulation (EU) 2016/425

**Type-examination by a notified body (Modul C)**

ÖTI – Institut für Ökologie, 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-examinations 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 effectiveness 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:

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