TECHNICAL DOCUMENTS FOR PPE

1. **Applicant / Distributor**

|  |
| --- |
| 🞎 **Manufacturer**  🞎 **Authorised representative** 🞎 **Importer** 🞎 **Trader**  🞎 **Distributor** *(mark the appropriate checkbox)* |
| Company  Sam Samplestreet 123  1000 Sample Place  AUSTRIA |

1. **Manufacturer**

|  |
| --- |
| **Manufacturing company / Place of Manufacturing** |
| Design-Company  Sam Samplestreet 123  1000 Sample Place  AUSTRIA |

# Description of the PPE

*Explanation: Descriptions as used in the manufacturer’s instruction and information  
PLEASE TAKE NOTE: The description of the PPE set out in this document is used in the type examination certificate.*

# Standards and directives

# Applied harmonised standards, technical specifications and directives *[Regulation (EU) 2016/425* Annex *III points. c) & g)]*

**PPE Regulation (EU) 2016/425**

**EN**

**EN**

# References of the harmonised standards *[Regulation (EU) 2016/425 Annex III point f)]*

Official Journal of the European Union regarding the:  
“Publication of titles and references of harmonised standards under Union harmonisation legislation”   
in their currently valid version.

*Source:*

|  |  |  |
| --- | --- | --- |
| *Internet* | *<http://eur-lex.europa.eu/homepage.html>* | |
| *Schnellsuche Quick search* | *Mitteilung der Kommission im Rahmen der Durchführung der Richtlinie 89/686/EWG des Rates zur Angleichung der Rechtsvorschriften der Mitgliedstaaten für persönliche Schutzausrüstungen (Veröffentlichung der Titel und der Bezugsnummern der harmonisierten Normen im Sinne der Harmonisierungsrechtsvorschriften der EU)Text von Bedeutung für den EWR.* | *Commission communication in the framework of the implementation of the Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (Publication of titles and references of harmonised standards under Union harmonisation legislation)Text with EEA relevance.* |
| *Suche eingrenzen Refine query* | 🗷 *Nach Jahr des Dokuments (z.B. 2017)*  🗷 *Nach Bereich (Amtsblatt)*  🗷 *Autor: Europäische Kommission* | 🗷 *By year of document (e.g. 2017)*  🗷 *By domain (Official Journal)*  🗷 *Author: European Commission* |
| *Sortieren nach:  sort by:* | *Datum des Dokumentes (Absteigend)* | *Document date (Descending)* |

# Intended & normally foreseeable use *[Regulation (EU) 2016/425 Annex II Preliminary Remarks point 5 & Annex III point a)]*

*Explanation: When designing and manufacturing the PPE, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the PPE, but also the reasonably foreseeable uses. Where applicable, the health and safety of persons other than the user shall be ensured*

e.g. see user-information

# Risk assessment

# Assessment of the risks against which the PPE is intended to protect, *[Regulation (EU) 2016/425 Annex III point b)]*

*Explanation: PPE must be classified in accordance to the risk categories set out in Regulation (EU) 2016/425 Annex I.*

|  |  |  |
| --- | --- | --- |
| *Category* | *Risks* |  |
| *Cat. I* | *Minimal risks* | *a) superficial mechanical injury;*  *b) contact with cleaning materials of weak action or prolonged contact with water;*  *c) contact with hot surfaces not exceeding 50 °C;*  *d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);*  *e) atmospheric conditions that are not of an extreme nature.* |
| *Cat. II* | *Category II includes risks other than those listed in Categories I and III;* | |
| *Cat. III* | *Risks that may cause very serious consequences*  *such as death or irreversible*  *damage to health* | *a) substances and mixtures which are hazardous to health;*  *b) atmospheres with oxygen deficiency;*  *c) harmful biological agents;*  *d) ionising radiation;*  *e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;*  *f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less;*  *g) falling from a height;*  *h) electric shock and live working;*  *i) drowning;*  *j) cuts by hand-held chainsaws;*  *k) high-pressure jets;*  *l) bullet wounds or knife stabs;*  *m) harmful noise.* |

|  |  |
| --- | --- |
| **Risk against which PPE protects:** |  |
| **Category of risk:** | **🞏 Category I**  **🞏 Category II**  **🞏 Category III** |

* 1. **Assessment of the risks which apply to the PPE,***[Regulation (EU) 2016/425 Annex II Preliminary Remarks point 4)]*

*Explanation: The manufacturer shall carry out a risk assessment in order to identify the risks which apply to his PPE. He shall then design and manufacture it taking into account that assessment*

***Risk assessment***

e.g. Compatibility with other PPE (e.g. jacket & pants; PPE & respiratory protection; etc.)

e.g. Overheating ...

* 1. **Applied essential health and safety requirements**  *[Regulation (EU) 2016/425 Annex III point c)]*

*Explanation: List of the essential health and safety requirements based on EU regulation 2016/425 Annex II, applicable to PPE.*

*Examples: ● Ergonomics*

* *Levels and classes of protection*
* *Innocuousness of PPE*
* *Comfort and effectiveness*
* *Manufacturer's instructions and information*
* *etc.*

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Requirement | |
| **section** | **List of essential health and safety requirements applicable to PPE (according to PPE REGULATION (EU) 2016/425 ANNEX II)** | standard *(optional)* | applicable *(tick appropriate*) |
|  |  |  |  |
| **1.** | **GENERAL REQUIREMENTS APPLICABLE TO ALL PPE** | | |
| 1.1. | Design principles |  | x |
| 1.1.1. | Ergonomics |  | x |
| 1.1.2. | Levels and classes of protection |  | x |
| 1.1.2.1. | Optimum level of protection |  | x |
| 1.1.2.2. | Classes of protection appropriate to different levels of risk |  | x |
| 1.2. | Innocuousness of PPE |  | x |
| 1.2.1. | Absence of inherent risks and other nuisance factors |  | x |
| 1.2.1.1. | Suitable constituent materials |  | x |
| 1.2.1.2. | Satisfactory surface condition of all PPE parts in contact with the user |  | x |
| 1.2.1.3. | Maximum permissible user impediment |  | x |
| 1.3. | Comfort and effectiveness |  | x |
| 1.3.1. | Adaptation of PPE to user morphology |  | x |
| 1.3.2. | Lightness and strength |  | x |
| 1.3.3. | Compatibility of different types of PPE intended for simultaneous use |  |  |
| 1.3.4. | Protective clothing containing removable protectors |  |  |
| 1.4. | Manufacturer's instructions and information |  | x |
|  |  |  |  |
| **2.** | **ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE** | | |
| 2.1. | PPE incorporating adjustment systems |  |  |
| 2.2. | PPE enclosing the parts of the body to be protected |  |  |
| 2.3. | PPE for the face, eyes and respiratory system |  |  |
| 2.4. | PPE subject to ageing |  |  |
| 2.5. | PPE which may be caught up during use |  |  |
| 2.6. | PPE for use in potentially explosive atmospheres |  |  |
| 2.7. | PPE intended for rapid intervention or to be put on or removed rapidly |  |  |
| 2.8. | PPE for intervention in very dangerous situations |  |  |
| 2.9. | PPE incorporating components which can be adjusted or removed by the user |  |  |
| 2.10. | PPE for connection to complementary equipment external to the PPE |  |  |
| 2.11. | PPE incorporating a fluid circulation system |  |  |
| 2.12. | PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety |  |  |
| 2.13. | PPE capable of signalling the user's presence visually |  |  |
| 2.14. | Multi-risk PPE |  |  |
|  |  |  |  |
| **3.** | **ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS** | | |
| 3.1. | Protection against mechanical impact |  |  |
| 3.1.1. | Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle |  |  |
| 3.1.2. | Falls |  |  |
| 3.1.2.1. | Prevention of falls due to slipping |  |  |
| 3.1.2.2. | Prevention of falls from a height |  |  |
| 3.1.3. | Mechanical vibration |  |  |
| 3.2. | Protection against static compression of a part of the body |  |  |
| 3.3. | Protection against mechanical injuries |  |  |
| 3.4. | Protection in liquids |  |  |
| 3.4.1. | Prevention of drowning |  |  |
| 3.4.2. | Buoyancy aids |  |  |
| 3.5. | Protection against the harmful effects of noise |  |  |
| 3.6. | Protection against heat and/or fire |  |  |
| 3.6.1. | PPE constituent materials and other components |  |  |
| 3.6.2. | Complete PPE ready for use |  |  |
| 3.7. | Protection against cold |  |  |
| 3.7.1. | PPE constituent materials and other components |  |  |
| 3.7.2. | Complete PPE ready for use |  |  |
| 3.8. | Protection against electric shock |  |  |
| 3.8.1. | Insulating equipment |  |  |
| 3.8.2. | Conductive equipment |  |  |
| 3.9. | Radiation protection |  |  |
| 3.9.1. | Non-ionising radiation |  |  |
| 3.9.2. | Ionising radiation |  |  |
| 3.9.2.1. | Protection against external radioactive contamination |  |  |
| 3.9.2.2. | Protection against external irradiation |  |  |
| 3.10. | Protection against substances and mixtures which are hazardous to health and against harmful biological agents |  |  |
| 3.10.1. | Respiratory protection |  |  |
| 3.10.2. | Protection against cutaneous and ocular contact |  |  |
| 3.11. | Diving equipment |  |  |

# Information on all the materials used

*Explanation: List of all materials used (outer shell, membranes, lining fabric, reinforcements, reflective stripes, zippers, buttons, buckles, sewing thread and other accessories, etc.) separately.*

# Shell

Manufacturer:

Article description:

Colour:

Material composition:

Weight per unit area:

Other information:

# Lining

Manufacturer:

Article description:

Colour:

Material composition:

Weight per unit area:

Other information:

# Liner

# Zipper

# Yarn

# Description of the PPE (clothing design) and of its intended use *[Regulation (EU) 2016/425 Annex III point a)]*

# Description of clothing design and *[Regulation (EU) 2016/425 Annex III point a)]*

*Explanation: Separately when there are individual pieces like jackets and trousers. The description must show the clothing design including seams, especially multilayer and overlapping structures of material layers must be clearly identifiable.*

# e.g. jacket

# e.g. trousers

# Other

# Sketch (design and production drawings of the PSA) *[Regulation (EU) 2016/425 Annex III point d) & e)]*

*Explanation: the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE (if necessary)*

# e.g. jacket

# e.g. trousers

# Other

1. **PPE produced as a single unit to fit an individual user  
   *(if necessary, otherwise this item may be deleted)***

*Explanation:* ***Required for mass-produced PPE, where each unique item is adapted to an individual user****, a description of the measures to be taken by the manufacturer during the assembly and manufacturing process to ensure that each copy of PPE with the approved type complies with applicable basic health and safety requirements*

# Instructions for the manufacturing of a PPE produced as a single unit to fit an individual user *[Regulation (EU) 2016/425 Annex III point l) & Annex V point 3 d)]*

# Instructions for the manufacturing of a PPE produced in series where each item is adapted to fit an individual user *[Regulation (EU) 2016/425 Annex III point m)]*

# Sizes and control measurement

*Explanation: Specification of the planned sizes with size specifications pursuant to EN ISO 13688 or alternatively pursuant to the standard given in the respective required standard (e.g. EN 340) and classification of the essential finished measurements. Separate for each piece of clothing.*

# e.g. jacket

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Body size (label) |  |  |  |  |  |
| Height |  | 172-176 | 176-180 |  |  |
| Chest measurement |  | 98-102 | 102-106 |  |  |
|  |  |  |  |  |  |
| Control measurement |  |  |  |  |  |
| Chest measurement |  | 116 | 120 |  |  |
| Back length |  | 85 | 89 |  |  |
| Sleeve length |  | 60 | 62 |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Dimensions are given in [cm] Tolerance: ± 2%, at least ± 2 cm

# e.g. trousers

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Body size (label) |  |  |  |  |  |
| Height |  | 172-176 | 176-180 |  |  |
| Waist measurement |  | 90-94 | 94-98 |  |  |
|  |  |  |  |  |  |
| Control Measurements |  |  |  |  |  |
| Waistband |  | 92 | 96 |  |  |
| Side length |  | 85 | 89 |  |  |
| Cut length with waistband |  | 106 | 109 |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Dimensions are given in [cm] Tolerance: ± 2%, at least ± 2 cm

# Others

# Label design

*Explanation:*

* *Labelling must include the following information as minimum requirements:*
* *Manufacturer or distributor (full address)*
* *Clear designation of product type / item number*
* *CE-labelling*
* *Reference to parts to be used together*
* *Information on protection and protection level through number of the standard and pictogram*
* *Size information with pictogram pursuant to EN ISO 16388*
* *Care label*
* *Possibly reference to user information (pictogram)*

# e.g. jacket

# Trousers

# Other

# Description of the internal final inspection *[Regulation (EU) 2016/425 Article 19 point b) & Annex III point j) & Annex VI (Module C; for PPE of der Category II) & Annex VII (Module C2; for PPE of der Category III)]*

*Explanation: A description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications.*

# Test reports on material testing *[Regulation (EU) 2016/425 Annex III point i)]*

*Explanation:*

* *reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class.*
* *The connection between the results in the test reports and the respective materials in the model must be evident.*

The following test reports were submitted to substantiate the product properties: (testing centre, test number)

# Manufacturer's instructions and information (Manufacturer's instructions and information) *[Regulation (EU) 2016/425 Annex III point k) & Annex II number 1.4)]*

*Explanation: In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE based on PPE-Regulation (EU) 2016/425 Annex II number 1.4) must contain all relevant information on:*

*a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;*

*b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;*

*c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;*

*d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;*

*e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;*

*f) where applicable, the type of packaging suitable for transport;*

*g) the significance of any markings (see point 2.12);*

*h) the risk against which the PPE is designed to protect;*

*i) the reference to this Regulation* (<http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:31989L0686&qid=1462893403477>) *and, where applicable, the references to other Union harmonisation legislation;*

*j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;*

*k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;*

*l) the internet address where the EU declaration of conformity* *[internal remark: Article 15 EU declaration of conformity]* *can be accessed.*

*The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.*

*In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE based on PPE-Regulation (EU) 2016/425 Annex II number 1.4) must contain all relevant information.*

***EU declaration of conformity (formerly declaration of compliance)***

***(pursuant to article 15 and Annex IX of PPE- REGULATION (EU) 2016/425)***

The EU declaration of conformity must include the following points in accordance with **Article 15 of PPE REGULATION (EU) 2016/425**

*Article 15 (Sec. 1) The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.*

*Article 15 (Sec. 2) The EU declaration of conformity shall have the model structure set out in Annex IX, shall contain the elements specified in the relevant modules set out in Annexes IV, VI, VII and VIII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is placed or made available on the market.*

*Article 15 (Sec. 3) Where PPE is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.*

*Article 15 (Sec. 4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the PPE with the requirements laid down in this Regulation.*

Furthermore the EU declaration of conformity must contain the following points in accordance with **Annex IX of PPE REGULATION (EU) 2016/425**

*1. PPE (product, type, batch or serial number):*

*2. Name and address of the manufacturer and, where applicable, his authorised representative:*

*3. This declaration of conformity is issued under the sole responsibility of the manufacturer:*

*4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):*

*5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: …*

*6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:*

*7. Where applicable, the notified body … (name, number) … performed the EU type-examination (Module B) and issued the EU type-examination certificate … (reference to that certificate).*

*8. Where applicable, the PPE is subject to the conformity assessment procedure … (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) … under surveillance of the notified body … (name, number).*

*9. Additional information:  
Signed for and on behalf of: …  
(place and date of issue):  
(name, function) (signature):*

**EU Declaration of Conformity No. …** (1)

Object of the declaration is the following personal protective equipment (PPE) **[Annex IX, Pt. 1]**

**Product:** **Jacket  
Type:** **Type XY** *(if applicable)* **Batch:** **123456** *(if applicable)* **Serial number:** **0815** *(if applicable))*

Manufacturer (a*nd, where applicable, its authorised representative*) **[Annex IX, Pt. 2]**

**Manufacturer** ***Representative*** *(if applicable)*  
**Company Mustermann XYZ** **Company *Mustermann ABC*Address** ***Address***

This declaration is issued under the sole responsibility of the manufacturer **[Annex IX, Pt. 3]**

The object of the declaration above is in conformity with the relevant Union harmonisation legislation: **[Annex IX, Pt. 4 & 5]**

**Regulation (EU) 2016/425 personal protective equipment**

Conformity is shown by compliance with the applicable requirements of the following documents **[Annex IX, Pt. 6]**

**EN ISO 13688:2013 Protective clothing – General requirements**

**EN ISO 11611:2015 Protective clothing for use in welding and allied processes**

**EN ISO 11612:2015 Protective clothing - Clothing to protect against heat and flame**

**EN ISO 14116:2015 Protective clothing – Protection against heat and flame – Limited flame spread materials, material assemblies and clothing**

The notified body **[Annex IX, Pt. 7]**

**OETI - Institut fuer Oekologie, Technologie und Innovation GmbH  
A-1230 Vienna, Siebenhirtenstrasse 12A; Objekt 8  
Notified Body No. NB 0534**

performed the EU type-examination (Module B) and issued the

**EU type-examination certificate XXXXXXXX**

The PPE is subject to the following conformity assessment procedure: **(für PSA der Kategorie III)** **[Annex IX, Pt. 8]**

Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body **OETI - Institut fuer Oekologie, Technologie und Innovation GmbH, Notified Body No. NB 0534**

Signed for and on behalf of:  **Manufacturer / Representative[Annex IX, Pt. 9]**

Place and date of issue: **Place, TT.MM.JJJJ**

Name, function: **Max Mustermann; function**

Signature: **……………………………………**

(1) It is optional for the manufacturer to assign a number to the declaration of conformity.