Manual for ITC's clients, 2018

Conformity assessment of PERSONAL PROTECTIVE EQUIPMENT pursuant to Regulation (EU) 2016/425.

Institute for Testing and Certification, inc., Czech Republic





1. Introduction

The present Manual aims at facilitating customers of the Institute for Testing and Certification, a.s. (hereinafter referred to as only „ITC“) to prepare documents necessary for conformity assessment of personal protective equipment (hereinafter referred to as only „PPE“) and providing them with the essential information about their rights and obligations in placing PPE on the EU market.

ITC is a legal entity authorized to perform activities in conformity assessment of PPE placed on the markets of member states of the European Union and countries of the European Free Trade Association and notified for this activity by the European Commission as Notified Body No. 1023 (hereinafter referred to as only „NB 1023“).

Technical requirements for PPE and obligations of persons introducing PPE into the market of the European Union are laid down by the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

2. Application

- The application form can be downloaded from the website **www.itczlin.cz**.
  - ⇨ Application for EU Type-Examination of PPE
  - ⇨ Application for the approval of quality control system for Category III PPE
- The client should deliver the completed form in person, by post, fax or email to one of the contacts below:

Institute for Testing and Certification, inc.
Certification Division

Dipl. Ing. Ludmila Antošová, Head of PPE division
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Specialists:

Dipl. Ing. Elena Tomanová: body protection, hand and arm protection, eye protection.
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Dipl. Ing. Miroslava Dostálová: foot and leg protection, PPE against risks arising from sports activity
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Dipl. Ing. Irena Látalová: body protection
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- It is advisable to deliver test samples and technical documentation along with the application - see the Articles 5 and 6;
- The application and submitted documentation shall be in the English language. Other official languages of the European Union may be used only upon agreement with ITC;

- In case of any issues, the application completion can be consulted with our experts, on the above-mentioned contact addresses;
- The EU legislation does not allow the manufacturer or authorized representative to file an application for service of an authorized or notified body for the same product with other entities.

3 Order (application) review

- The order (application) is reviewed in terms of accuracy and completeness of data and it is registered.
- If the order (application) or the submitted documentation is incomplete, ITC specifies the missing items in writing (by letter, email or fax) and requires completion of the details.

4 Determination of price and delivery date

- The service price and delivery date are usually calculated after providing all the details necessary for specification of the range of expert works – such as test samples and technical documentation.

5 Technical documentation

The technical documentation shall include at least the following elements:

- a complete description of the PPE and of its intended use;
- an assessment of the risks against which the PPE is intended to protect;
- a list of the essential health and safety requirements that are applicable to the PPE;
- design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
- 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;
- the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
- where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
- the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
- 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;
- 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;
- a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
- for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
- or PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

  These instructions must be precise and comprehensible and must be drawn up at least in the official language or languages of the member states for which they are intended.

6 Test samples

- Optimally, samples should be supplied together with the application. However, they can also be provided later, upon agreement with contact persons.
- The samples of the PPE must represent the type intended for EC examination. The same "type" may include several versions (models) of the product provided that the differences between the versions affect neither safety level, quality characteristics, nor the product intended use. Particularly, the PPE of the same type must be manufactured from the same materials, using identical technology and they must be based on identical designs.
- Assessment of the effect of deviations of various versions on safety and quality levels and on intended use of the product is the exclusive authority of NB 1023.

7 Contract

- The commercial relationship between the client and ITC is negotiated according to the nature, demandingness and price level of the service - order.
- In case of the orders of the notified body, contracts containing the following details are concluded with the clients:

  - The contract usually contains:
    - specification of the contractual parties;
    - range of contracted works;
    - price information and terms of payments;
    - delivery date of the service;
    - breach of contractual obligations and consequences thereof;
    - rules for withdrawal from the contract.

- Commencement of works is subject to bilateral written approval of conditions of co-operation and payment of a pro-forma invoice. Advance payments are requested from all clients, with some exceptions, which are agreed in special framework agreements on cooperation.

8. PPE Classification

- According to dependence on the extent of a potential hazard associated with the use of a product the PPE is divided into three groups (categories).
- Inclusion of a PPE into the particular categories is by law manufacturer's or importer's job. In case of doubts the categorization can be consulted with the appropriate notified body.

8.1 PPE – category one

- Personal protective equipment of a simple design where the manufacturer or importer can assume that the user can himself/herself assess the level of protection provided against risks that can be safely identified by the user in good time. It includes for instance PPE intended to protect the wearer against mechanical action the effects of which are superficial (e.g. gardening gloves), against temperatures up to 50 °C, influences of atmospheric agents not extreme in nature, minor impacts or sunlight (e.g. sun glasses).

8.2 PPE – category three

- PPE intended to protect life or to protect against risks that may seriously and permanently harm the health, and where the manufacturer or importer may assume that the user will be unable to identify these dangers in good time. This category cover PPE for protection of respiratory system, protection against temperatures exceeding 100 °C or lower than –50 °C, all PPE for protection against fall, PPE against harmful biological agents, PPE against substances and mixtures which are hazardous to health, PPE against hand-held chain-saws etc.

8.3 PPE – category two

- The remaining personal protective equipment that, by its character, does not comply with the definition of either category one or three, is covered by category two.

9. Conformity assessment procedures for separate categories

- For separate PPE categories the Regulation prescribes various conformity assessment procedures. A chart of the procedures that will apply in separate categories of personal protective equipment is shown in the following table. The table may simultaneously be used as an aid for the manufacturer in PPE categorization and deciding which of the alternative assessment procedures for Category III personal protective equipment to choose.

Table: A scheme of procedures for PPE conformity assessment

<table>
<tr><td colspan="4">Manufacturer or importer will decide whether the PPE is of a simple design</td></tr>
<tr><td colspan="2">Yes
Category I PPE</td><td colspan="2">No
Category II or III PPE</td></tr>
<tr><td rowspan="5" colspan="2">The manufacturer (importer) will compare properties of the PPE with essential require-ments of the Annex II of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC and collect the needed technical documentation according to Annex III</td><td colspan="2">The manufacturer (importer) will collect the necessary technical documentation according to Annex III of the Regulation (EU) 2016/425 and present it to the authorized body together with the Application for Conformity Assessment.</td></tr>
<tr><td colspan="2">The authorized body will carry out EU Type-Examination pursuant to Annex V of the Regulation (EU) 2016/425</td></tr>
<tr><td colspan="2">Manufacturer (importer) will decide whether the PPE is intended for protection of life and protection against risks that may seriously and permanently harm the health.</td></tr>
<tr><td>No
Category II PPE</td><td colspan="2">Yes
Category III PPE</td></tr>
<tr><td colspan="2">Manufacturer (importer) selects method of yearly check (inspection).</td></tr>
<tr><td colspan="2"></td><td>Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2 see Annex VII of the Regulation)</td><td>Conformity to type based on quality assurance of the production process (Module D see Annex VIII)</td></tr>
<tr><td colspan="4">Manufacturer (importer) will issue a EU Declaration of Conformity and mark every product by CE marking</td></tr>
</table>

- If the manufacturer chooses the Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) he must ensure the homogeneity of production and select a notified body that will carry out random checks and tests of the manufactured PPE at intervals shorter than one year.
- If the manufacturer selects the Conformity to type based on quality assurance of the production process (Module D) he must have the system already implemented or he must implement it.
- The notified body will verify the production quality system and ascertain, through a supervision, whether the manufacturer maintains the system in the state in which it was verified.

10 Rules for recognition of results from the documentation submitted by the Applicant

- Recognition of results obtained by other laboratories and presented in the documentation depends solely on the decision of ITC;
- Usually, results given in tests reports of accredited laboratories are recognized provided that no more than 5 years have elapsed from the issuance date of the report;
- In principle, results of tests carried out in the manufacturer′s or non-accredited laboratories are not recognized. Tests carried out on unique testing equipment, which is not commonly accessible, may constitute an exception. In such cases, ITC prefers conducting the test under supervision of its own experts.

11 Related services of ITC

- PPE testing in the Accredited laboratory No. 1004 and No. 1004.3;
- Granting a license for the voluntary certification mark "ITC Certified Quality", which is granted to products where high level of safety and quality parameters was proved by certification and where the manufacturer′s capability to continuously maintain the quality was proved by inspection visits;
- Standardization services and technical information;
- Management systems certification (ISO 9001, ISO 14001, OHSAS 18001);
- Technical inspection;
- Laboratory and certification documents as a basis of selection procedures, tender

12 Annexes

- Annex No.1: ITC's notification in the area of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC
- Annex No.2: Definitions

Annex 1 ITC´s notification in the area of the Regulation (EU) 2016/425 of the European Parliament and of the Council

ITC's notification in the area of the Regulation (EU) 2016/425 of the European Parliament and of the Council covers PPE classes as follows:

Specification according to body parts:

- Equipment providing chest and groin protection
- Equipment providing eye protection
- Equipment providing face protection
- Equipment providing foot, leg and anti-slip protection
- Equipment providing general body protection (clothing)
- Equipment providing hand and arm protection
- Equipment providing hand and arm protection against chemical agents
- Equipment providing protection against cold [cold >-50°C], [extreme cold <-50°C]
- Equipment providing protection against heat [Heat <100°C], [Heat >100°C and fire]

Specification according to risks:

- Protective Equipment against electric shock
- Protective Equipment against hand-held chain-saws
- Protective Equipment against harmful biological agents
- Protective Equipment against mechanical risks
- Protective Equipment against non-ionising radiation
- Protective Equipment against slipping
- Protective Equipment against static compression
- Protective Equipment against vibrations
- Protective Equipment against chemical agents
- Protective Equipment against risks from sports activity

Specialized areas of competence:

- Body armour
- Protective clothing against static electricity
- Protective clothing for use in welding and allied processes
- Firemen suits
- High visibility clothing
- Protective equipment for use in potentially explosive atmospheres

Annex 2 Definitions

Basic terms

- **Personal protective equipment**
  a) 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;
  b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;
  c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.

- **CE conformity marking**
  Marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

- **Essential requirements**
  Technical requirements for products the meeting of which is a prerequisite for a minimum sufficient safety of a product provided they are used in a usual and reasonably foreseeable manner. They are defined in the Annex II of the Regulation (EU) 2016/425 . The most frequent method of demonstration of the conformity with the essential requirements is a demonstration of conformity with the harmonized standard related to the product.

- **Harmonized technical standard**
  European standard adopted on the basis of a request made by the Commission for the application of Union harmonization legislation.

- **Notified body**
  A body authorized to defined activities in conformity assessment of products specified by a national authority (in case of the Czech Republic by Úřad pro technickou normalizaci, metrologii a státní zkušebnictví – ÚNMZ /Office for Standards, Metrology and Testing/) and notified to European Commission bodies and to all EU member states as a body authorized to carry out activities in conformity assessment of products for which it received the notification. Decisions and documents issued by all notified bodies (NB) are equal and valid in the entire EU.

- **Conformity assessment**
  The process demonstrating whether the essential health and safety requirements of the Regulation (EU) 2016/425 of the European Parliament and of the Council relating to PPE have been fulfilled.

- **EU type-examination**
  Part of a conformity assessment procedure in which a notified body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the requirements of the Regulation (EU) 2016/425 of the European Parliament and of the Council that apply to it.

- **Notification scope**
  Specific definition of the range of products and conformity assessment procedures for which the given NB, based on a demonstration of a professional and technical competence, is notified and authorized to conduct its activities.

- **Authorized representative**
  Any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks.

- **Placing a product on the market**
  The first making available of PPE on the Union market.