# PROCEDURE 16.03

# Technical Documentation for PPE



**INDEX**



| Rev. | Issuing date | Revision reason | Drafted by RSGQ | Verified by DOC | Approved by DIRECTION |
|---|---|---|---|---|---|
| 2 | 01/05/2018 | Second revision | Zenarolla A. | Sommariva G. | Boito L. |

## 1 Scope

To describe the information that shall be included in the Technical Documentation for PPE, written by the manufacturer, for the EU type-examination regarding Personal protective Equipment (herewith defined as PPE), as provided for by Regulation (EU) 2016/425.

## 2 Applicability

This procedure - intended as a guide for the manufacturer - is useful for the drawing up of the Technical Documentation for PPE, for the aim of the EU type-examination, and is useful for Certottica in conducting the evaluation of the contents of the Technical Documentation submitted by the manufacturer.

## 3 Reference documentations

For the activities covered by this procedure, reference is made to the following documentations:

- 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;
- EN 45020:2007 “Standardization and related activities. General vocabulary";
- ISO/IEC 28:2004 “Conformity assessment -- Guidance on a third-party certification system for products";
- ISO/IEC 17065:2012 Conformity assessment. Requirements for bodies certifying products, processes and service;
- Technical sheets for coordination of Notified Bodies horizontal recommendation for use sheets (RfUs);
- Blue Guide of the Commission notice of 5.4.2016 on the implementation of the EU product rules 2016;
- PPE Regulation (EU) 2016_425 Guidelines - 1st Edition - April 2018;
- Horizontal recommendation for use sheets (RfUs) of the European Coordination of Notified Bodies in the field of PPE regulation (EU) 2016/425.

## 4 Composition of the Technical Documentation for PPE

The Technical Documentation for PPE may consists of a single document, as well as of a collection of documents. Regardless the structure of the Technical Documentation for PPE, it should be possible to identify any updating of the Technical Documentation, or of each individual document, with the inclusion of the revision index and/or the presence of an issuing date.

In the case where a product has been subject to re-designs and re-assessments of the conformity, the technical documentation must reflect all versions of the product; describing the changes made, how the various versions of the product can be identified and information on the various conformity assessment. This is to avoid situations where during the whole life of a product, a market surveillance authority is faced with

previous versions of the product for which the version of the technical documentation it is presented with, is not applicable.

### 4.1 Information provided

The Technical Documentation for PPE shall include, at least, the elements provided for by Annex III of the Regulation (EU) 2016/425.

The following elements shall, at least, be included:

a) a complete description of the PPE and of its intended use;
b) an assessment of the risks against which the PPE is intended to protect;
c) a list of the essential health and safety requirements that are applicable to the PPE;
d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
e) 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;
f) 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;
g) 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;
h) 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;
i) 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;
j) 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;
k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
l) 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;
m) for 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.

The details of the information depends on the type of PPE, the category therefore the associated risk.

*4.1.1 Complete description of the PPE and of its intended use*

Within the Technical Documentation, the PPE shall be clearly and uniquely identified. For this purpose, the following information should be included:

- description of the PPE;
- intended use;
- PPE costituent materials;
- applicable protective requirements and any limitation of use, where applicable;
- any result of the design calculation/inspections carried out in the prototype;
- product marking and its location on the PPE;
- description of any PPE variant and its protective requirements, where applicable;
- one or more photographic image(s) of the PPE, possible in each variant;
- dimensioned drawing and/or schemes of the PPE including main dimensions;

As provided for by PPE-R/00.037, the generally accepted action in order to verify that a PPE model has been produced in accordance with the manufacturer's technical documentation is to conduct a visual comparison between an example of the model and a description of the model. The objective of the comparison is to ensure that, in general terms, the product is as described and that there are no obvious differences in general form or materials.

*4.1.2 Requirements for basic health and safety requirements*

Manufacturers shall define the lists of basic health and safety requirements that are applicable to its PPE, in compliance with Annex II of the Regulation (EU) 2016/425.

Therefore, manufacturers have to carry out a risk analysis to first identify all possible risks that the product may pose and determine the essential requirements applicable. This analysis has to be documented and included in the Technical Documentation. In addition, the manufacturer needs to document the assessment of how he is addressing the risks identified to ensure that the product complies with the applicable essential requirements (for example, by applying harmonised standards).

Harmonised standards, which title is published in the OJEU, cover essential health and safety requirements it aims to cover. The relevant essential or other legal requirements aimed to be covered are usually indicated in a separate informative Annex (ZA) to a harmonised standard.

The application, as technical solution, of any harmonised standard gives presumption of conformity with the essential or other requirements it aims to cover (see Annex ZA).

Harmonised standards maintain their status of voluntary application.

If only part of the harmonised standard is applied, or it does not cover all applicable essential requirements, then the way applicable essential requirements not covered by it are dealt with, shall be documented.

*4.1.3 Internal production control*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of the Regulation (EU) 2016/425.
Within the Technical Documentation shall, therefore, be included 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.
The level of details to be included is strictly connected to the complex of the PPE and its protective requirements.

*4.1.4 Manufacturer's instruction and information.*

Manufacturers shall ensure that the PPE, is accompanied by the instruction and information as set out in point 1.4 of Annex II in a language that can be easily understood by consumer and other end-users, as determined by the Member State concerned. Each harmonised standard, if applied, does include its own information.
Clear, understandable and legible copy of Manufacturer's instruction and information shall be included in the Technical Documentation for PPE in order to let Certottica check for its suitability.
Any translation of Manufacturer's instruction and information is responsibility of the manufacturer / authorized representative.

### 4.2 Additional information

Above information may be integrated with the following elements:

- a trademark declaration related to the PPE as placed on the market:
  - in such cases where the trademark is not owned by the manufacturer, then the license agreement between the trademark owner and the manufacturer should also be included;
- Material Safety Data Sheets (MSDS) of constituent materials and/or a written confirmation that the submitted PPE does not contain any substances at levels that are known to, or suspected to, adverse affect user hygiene or health, as provided for by PPE-R/00.038.

### 4.3 Example of a Technical Documentation for PPE

Following is ax example of a Technical Documentation's structure. It shall be noted that this is just an example, and the final decision on how to structure the Technical Documentation for PPE is up to the manufacturer.

Example of Technical Documentation consisting of different sections:

- Section A, a complete description of the PPE and of its intended use;
- Section B, a list of applied basic health and safety requirements;
- Section C, copy of the Manufacturer's instruction and information;
- Section D, 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.
- Annex 1, Dimensioned drawing/schemes of the PPE ;
- Annex 2, Trademark declaration;
- Annex 3, Material Safety Data Sheets;

### 4.4 Storage Period of the Technical Documentation for PPE

The Technical Documentation for PPE must be kept for 10 (ten) years from the date of placing the product on the market.

## 5. Responsibility

The operational responsibility of all the phases relating to the drafting of the Technical Documentation for PPE is up to the manufacturer. CERTOTTICA'S Assessment Manager (RVAL) has the task of checking the content and exhaustiveness of the Technical Documentation for PPE, requiring any additions to the manufacturer, if necessary.

## 6. Quality records

The record of all the documentations produced belongs to the Head of the RSGQ and the Certification Services Manager.