Sommario

Revision	*Reason for modifications*	*Written by*	*Approved by*
3	Small changes	Flavio Banfi	Roberto Cusolito
4	Update identification of the technical file by the manufacturer (ref. NC 4 Internal audit PPE 2020)	Flavio Banfi	Roberto Cusolito

1 PREMISE

The Regulation UE 2016/425 requires that for PPE of II and III category the manufacturer shall submit to assessment the type of PPE before placing it on the market in the UE.
Evaluation procedures are described in Annex V of Regulation 425, EU type examination (module B).
Some parts of Annex V are reported:
(…) EU type-examination shall be carried out by assessment of the adequacy of the technical design of the PPE through examination of the technical documentation (…)
The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice. The application shall include: (…) (c) the technical documentation described in Annex III (…).
The notified body shall examine the technical documentation to assess the adequacy of the technical design of the PPE.
The aim of this document is therefore to provide a guideline for the manufacturers on how the technical documentation could be assembled and drafted to facilitate the evaluation activities and to ensure the coherence and availability of the documentation itself for any future requests.
It is also appropriate here to remember that among the obligations on the part of the manufacturers there is also (Article 8 paragraph 2) "*Manufacturers shall draw up the technical documentation referred to in Annex III".* The responsibility for drafting the technical documentation, to be understood as "issue" of the documentation, cannot be delegated (refer to article 9 paragraph 1).
Any changes made to the previous revision are identified with a sidebar on the right.

2 DOCUMENTATION STRUCTURE

The technical documentation must first of all be issued and managed according to the main documentation management rules. The following is therefore requested:

- The Technical File shall have an univocal identification. This can be done by means of an identification code (eg: FT01) or by referring to the model of the PPE (ex: technical file WHOLE MASKS). This identification can be used as a reference in the correspondence passed to and from ITALCERT.
- The Technical File shall have an issue date and/or a progressive review index. This identification must be updated before each submission to ITALCERT.
- The Technical File shall indicate the subject (or the subjects) who authorized the issue of the document itself.
- Where there are annexes to the technical file, the dossier must include the list of annexes in an index, correlating them with the respective current issue date. A modification of a single attachment also causes the revision of the Technical File revision to be updated.

The identification of the technical documentation is mentioned in the EU type certificates, as identification of the characteristics of the certified PPE. This is to mark the importance that the identification of the technical documentation must allow to identify, in the most linear way possible and univocally, the PPE and its configuration.
The Technical File shall be written in Italian and / or English. Other languages must be previously accepted by ITALCERT.
It is possible that the same Technical File encloses several models of PPE, provided they have elements in common such as: reference standard, type of protection, etc. If this is not possible, it will be necessary to issue more Technical File.

3 TECHNICAL FILE TRANSMISSION

The Technical File can be transmitted to ITALCERT in hard copy or in electronic form. In this second case it could be without the signature of the subject who authorized the issue of the technical file.
All files transmitted electronically must be in an non modifiable format (e.g. PDF, JPG). Therefore, files in "word" or "excel" format are not acceptable.
The Manufacturer is however required to keep a copy of the documentation formally approved according to the manufacturer's rules.

4 CONTENTS

The minimum elements required by Regulation 425 in Annex III are discussed below, with a brief comment where applicable.

4.1 A complete description of the PPE and of its intended use;

In general, the technical documentation is expected to start with an introduction illustrating the PPE and its intended use.
The intended use is an important element because it constitutes an entry point for the subsequent assessment of residual risks and, consequently, on the possible non-applicability of certain requirements or some requirements of the reference standards.

4.2 An assessment of the risks against which the PPE is intended to protect

As a next step it is necessary to identify what kind of protection should be offered by the PPE.
As an example, a PPE designed to protect the eyes could protect against shocks and / or sun radiation.
Clarifying this aspect is also important for a correct assessment of the applicable essential safety requirements (next step).

4.3 A list of the essential health and safety requirements that are applicable to the PPE

The Technical File shall include the list of the essential requirements identified by the Regulation in Annex II. For each of them, the manufacturer shall clarify the design choice that has been made to ensure the compliance of the PPE with these requirements.
It is recommended to organize the list as a matrix with, as an example, the following columns:

- Column A: The requirements identified in the Annex II
- Column B: if the requirement is applicable or not
- Column C: a brief description of the design solutions adopted
- Column D: a link to the relevant paragraph of the harmonized standard used as reference

It should be noted that all the CEN technical standards published in reference to regulation 425 or Directive 89/686 / EEC show in appendix ZA a correlation matrix between the safety requirements and the points of the standard itself.
However, it should also be taken into account the possibility that there are some requirements identified as applicable and not included in the aforementioned ZA table. Therefore full compliance with the harmonized standard used as a reference may not be sufficient to cover all applicable requirements.

4.4 Design and manufacturing drawings and schemes of the PPE and of its components

The Technical Documentation shall include, as applicable:

- At least an overall drawing
- One or more dimensioned drawings of the PPE and / or its components
- The list of components as well as the raw materials used
- Technical sheets of components and / or raw materials to demonstrate their characteristics (for example in terms of compatibility with the skin)

We want to focus that the identification of the characteristics of the certified type depends on the completeness of the information that is collected in relation to this point. It is therefore the primary interest of the manufacturer that this identification is the clearest and the most univocal possible.
It is usual, although obviously not mandatory, that the above documentation is considered as an annex to the technical documentation.

4.5 The descriptions and explanations necessary for the understanding of the drawings and of the operation of the PPE

On the basis of what is necessary and appropriate, the technical documentation could / should provide further clarifications that allow to understand the design choices. As an example, the choice of a certain raw material could be the subject of a further comment indicating that it was chosen for its lightness and ease of maintenance / cleaning.

4.6 The references of the harmonised standards that have been applied for the design and manufacture of the PPE

This information should be included in the introductory part, together with the description of the PPE.
Or it can be clarified as an introduction to the evaluation of the essential safety requirements.
The standard shall be mentioned with the year of publication.

4.7 Description of other technical specifications that has been applied in order to satisfy the applicable essential health and safety requirements

If the manufacturer considers to use more / different reference than the harmonized standard, this choice shall be clarified.

4.8 The results of the design calculations, inspections and examinations carried out

In principle, for II and III category PPE the duty to verify the conformity of PPE is borne by the Notified Body. However, in some situations it may be appropriate, if not necessary, for the manufacturer to demonstrate with his own documentation the compliance with some of the essential safety requirements.
By way of example, to demonstrate and support the compliance to requirement 2.6 (PPE intended to be used in potentially explosive atmospheres) the manufacturer could insert in the technical documentation some test reports made in his own name.

4.9 A description of the means used by the manufacturer during the production of the PPE

The manufacturer shall ensure his ability to mass-produce PPE conforming to the certified type.
In general, it is expected that the technical documentation will include, as applicable:

- A procedure that describes the production flow and control points
- A manufacturing and control plan applied in production.
- Planning of examinations and type checks; these tests are carried out by sampling, not necessarily on each lot produced. They constitute a repetition, even partial, of the tests carried out for certification.

The place where production and control is carried out, if different from one of the manufacturer's premises, must be identified. This can lead to the clear identification of the subjects used as outsourcers.

4.10 Manufacturer's instructions and information

The instructions and information shall at least include what is required by Regulation 425 in Annex II, point 1.4.
However, the specific requests contained in the standards used as reference should also be taken into account.
The instructions can be attached as a copy of the ones that will be used or even as an illustrative text.
Please note that the information provided by the manufacturer generally includes:

- Marking on the product
- Informative note
- Packaging

In order to manage any subsequent revisions, the information note should include an index of revision and / or issue date.