PROCEDURE 16.108.003

Technical Documentation

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Rev.	Date of issue	Reason for revision	Drawn up by Head of QMS	Checked by DOC	Approved by MANAGEMENT
1	15/05/2020	Updating of the procedure	RSGQ – Zenarolla A.	DTL – Tamburlin L.	DIR – Boito L.

1 Scope

Describing the information to be included in the Technical Documentation prepared by the Manufacturer for EU type-examination of Personal Protection Equipment (hereinafter PPE) as provided for by Regulation (EU) 2016/425.

2 Applicability

This procedure is to be applied as a guide for the Manufacturer in drawing up the Technical Documentation for the purpose of EU type-examination for PPE and as a guide for Dolomiticert in assessing the contents of the Technical Documentation presented by the Manufacturer.

3 Reference Documentation

For the activities included in this procedure reference is made to the documents listed below:

- 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
- UNI CEI EN 45020~~:2007~~ Standards "General terms and their definition regarding training and related activities"
- UNI CEI 70006 Standards "General rules for a standard product certification system by an independent body"
- EN 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)
- PPE Regulation (EU) 2016/425 Guidelines

4 Technical Documentation

The Manufacturer's Technical Documentation may be a single complete document or a collection of data sheets. In both cases, it must be possible to identify any updates of the document or single sheets through the attribution of a revision schedule and/or the provision of a date of issue. It's desirable, in addition, that all the pages of the technical documentation have the corresponding progressive number of page; otherwise, a progressive number will be applied by an operator of Dolomiticert, by hand or by means of a stamp equipped with progressive numbering.
Dolomiticert will accept Manufacturer's Technical Documentation only in Italian or English language.

4.1 Information required

The minimum content for Manufacturer's Technical Documentation for category II and III PPE is given in Annex III of the regulation (EU) 2016/425.
In particular the following information is required:

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 to 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 of the Regulation (EU) 2016/425;
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 degree of detail in the information given depends on the type of PPE, the class it belongs to and therefore the associated hazard.

4.1.1 General and detailed plans for the PPE

The Manufacturer's Technical Documentation relating to the PPE for which EU type-examination is required must be clearly and univocally defined. The following information may be provided for the purpose:

- device description;
- field, fields of use for which the device is designed;
- list of the materials used in the PPE;
- protection requirements, with limitations of use, if applicable;
- any calculation notes and/or results of tests on prototypes;
- marking and positioning and dimensions of marks on the PPE;

- description and protective characteristics of any variants to the PPE;
- images of the PPE and all its variants;
- drawings or images with measurements showing the main dimensions of the PPE.

The prototypes forwarded for testing or any proof sample pieces must be easily and univocally recognized.
The information provided must make it possible to identify the protective characteristics of the PPE so that they can be compared with the test results.

4.1.2 Health and safety requirements

When designing PPE the Manufacturer must analyse all the fundamental health and safety requirements applicable thereto. A list and description of these fundamental requirements is contained in Annex II of Regulation (EU) 2016/425. When the basic health and safety requirements applicable to the PPE in question have been identified, the Manufacturer must demonstrate conformity by listing all the technical measures taken to comply.
To facilitate the Manufacturer's task, the European Committee for Standardization (CEN) publishes harmonized European standards, on behalf of the European Commission. These harmonized European standards cover a series of basic health and safety requirements. A list of the requirements covered by harmonized standards is included in Annex ZA of the standards.
The application of harmonized European standards is voluntary. However, publishing a reference to the application of a harmonized European standard provides a presumption of conformity with the basic health and safety requirements included in Regulation (EU) 2016/425, which come within the field of application of the standards.
If the Manufacturer uses other technical specifications different from harmonized European standards, or applies only a part of such standards, he must demonstrate that the technical specifications adopted for assessment of conformity with the health and safety requirements in question are suitable for the purpose.
The Technical Documentation must show all the basic health and safety requirements taken into consideration by the Manufacturer when designing the PPE and provide references to the harmonized European standards used to demonstrate conformity, or the technical specifications employed, if these are different from those in the harmonized European standards, together with their suitability to demonstrate conformity with the requisite in question.

4.1.3 Description of applied control and test instruments

The Manufacturer shall guarantee that throughout the PPE production process quality and conformity with the contents of the Technical Documentation shall be maintained.
For this purpose, the Manufacturer must set up control stations along the PPE production line. To provide better understanding of the suitability of the controls in question it will be useful to indicate the different stages of production, starting with the purchase of raw materials and/or semi-finished parts from suppliers. The controls carried out, their purpose and the number of test pieces controlled should be indicated for each stage or group of stages. It will also be useful to note the instruments used for the controls and any procedures applied to them.
Therefore, the Technical Documentation should contain the following information:

- diagram showing the different production stages for the device;
- controls to be carried out during the different production stages;

- purpose of the control in question;
- frequency of controls.

If necessary, the above can also include:

- an indication of the instruments used for the different controls;
- procedures or instructions for use of the instruments.

The amount of detail in the above-mentioned information depends on the complexity and protective characteristics of the PPE.

4.1.4 Manufacturer's information notice

All PPE placed on the market must come with the Manufacturer's information notice. The contents of such instructions are explained in clause 1.4 of Annex II Regulation (EU) 2016/425. If harmonized European standards are applied, these set out the amount of detail in the information to be given.

A copy of the Manufacturer's information notice, clearly legible and easily uderstandable, must be included in the Technical Documentation in Italian or English, so that Dolomiticert can check the contents. It is the Manufacturer's task to provide a good translation of the Manufacturer's Instructions in the different official languages of the country where the devices will be used.

4.1.5 Risk assessment

The term "risk assessment" is used for the assessment and quantification of various risks associated with the use of PPE. The risk assessment defined in the Regulation (EU) 2016/425 should not be confused with the risk assessment that an employer is required to make in relation to health and safety at work legislation. The risk assessment defined as Regulation (EU) 2016/425 concerns only PPE and not working or use conditions.

The contents of the risk assessment can be summarized in two macro-areas.

a) *Risk assessment against which the PPE intends to protect.*
   The results of the risk assessment should be reflected in the technical documentation and also in the manufacturer's instructions and information so that the user is able to estimate the associated risk reduction when using the PPE (quantitatively or qualitatively) under the conditions of foreseeable use.

b) *Risk assessment relating to the use of PPE under foreseeable conditions of use*.
   Risk assessment should include:
   – maximum exposure to harmful agents to which the PPE provides protection (if applicable);
   – maximum protection time (if applicable);
   – environmental conditions that affect the effectiveness of the PPE (for example humidity, temperature, work, etc ...);
   – limitations of use;
   – identification of signs of loss of the protective function of PPE.

In order to identify the risks from which the PPE is intended to protect and related to the use of the PPE, taking into account all the phases of the foreseeable life of the PPE, the manufacturer or his authorized representative shall ensure that a risk assessment is carried out: the manufacturer is responsible for the contents of the risk assessment.

4.2 Additional information

The above-mentioned information must, if possible, also include the following:

- declaration of the trademark under which the PPE is sold;
  - if the trademark in question is not owned by the Manufacturer, the licence agreement between the trademark owner and the Manufacturer must be produced.
- Material safety data sheets (MSDS) for the materials of which the PPE is made, and/or declarations that the materials involved are safe for the user's health.

In the case of category III PPE subject to one of the controls mentioned in annexes VII or VIII of the Regulation (EU) 2016/425, the Technical Documentation could include, if the Client is preventively willing to communicate it, a declaration that identifies the notified body responsible for this control phase and the type of control (following the procedure defined in annex VII – Module C2 – or in the annex VIII – Module D – of the Regulation (EU) 2016/425).

4.3 Example of Manufacturer's Technical Documentation

Below is an example of possible Technical Documentation. It must be pointed out that this is merely an example and that in any case the Manufacturer will decide the structure of such documentation.

Example of Manufacturer's Technical Documentation, subdivided into sections:

- Section A, general and detailed plans for PPE;
- Section B, analysis of basic health and safety requirements;
- Section C, Manufacturer's information notice;
- Section D, description of manufacturing processes;
- Section E, control and test instruments;
- Appendix 1, technical drawings and/or images that identify the PPE;
- Appendix 2, trademark declaration;
- Appendix 3, materials safety data sheets;
- Appendix 4, declaration that identifies the notified body responsible for the product/production control of the PPE and the type of control, following the procedure defined in annex VII (Module C2) or in annex VIII (Module D) of the Regulation (EU) 2016/425.

4.4 Storage period for Manufacturer's Technical Documentation

It is generally accepted that the storage period for Manufacturer's Technical Documentation is ten years, starting from the most recent date of placing on the market for the PPE.

5. Responsibility

The Manufacturer is responsible for all the preparation stages of the Technical Documentation. It is the task of the person Responsible of the Evaluation (RVAL) of Dolomiticert to check the contents and comprehensiveness of the Technical Documentation and where necessary require integration by the Manufacturer.

6 Quality Control registration

All the documentation produced must be registered by the Head of the Quality Management System and the Certification Board Manager of the certification body of Dolomiticert.