PROCEDURE 16.108.003

Technical Documentation

CONTENTS

1 Scope

Describing the information to be included in the Technical Documentation prepared by the Manufacturer for UK type-examination of Personal Protection Equipment (hereinafter PPE) as provided for by Regulation 2016/425 on personal protective equipment as brought into UK law and amended.

2 Applicability

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

3 Reference Documentation

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

- Regulation 2016/425 on personal protective equipment as brought into UK law and amended
- EN 45020–Standards “General terms and their definition regarding training and related activities”
- ISO/IEC 17026 Conformity assessment - Example of a certification scheme for tangible products
- ISO/IEC 17065 Conformity assessment Requirements for bodies certifying products, processes and service.
- Technical sheets for coordination of Notified Bodies horizontal recommendation for use sheets (RFU’s)
- Regulation 2016/425 and the Personal Protective Equipment (enforcement) Regulation 2018 Guide v.4
- The National Accreditation Logo & Symbols: Conditions for use by UKAS and UKAS accredited organisations – January 2021

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 is 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 Certdolomiti, by hand or by means of a stamp with progressive numbering.

4.1 Information required

The minimum content for Manufacturer's Technical Documentation for category II and III PPE is given in Annex III of Regulation 2016/425 on personal protective equipment as brought into UK law and amended.
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 designated 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 designated standards, the documentation shall specify the parts which have been applied;
g) where designated 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 Regulation 2016/425 on personal protective equipment as brought into UK law and amended;
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 risk.

4.1.1 General and detailed plans for the PPE

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

- device description;
- field(s) 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 the 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 2016/425 on personal protective equipment as brought into UK law and amended. 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 designated standards, on behalf of the European Commission. These designated standards cover a series of basic health and safety requirements. A list of the requirements covered by designated standards is included in Annex ZA of the standards.
The application of designated standards is voluntary. However, publishing a reference to the application of a designated standard provides a presumption of conformity with the basic health and safety requirements included in Regulation 2016/425 on personal protective equipment as brought into UK law and amended, which come within the field of application of the standards.
If the Manufacturer uses other technical specifications different from designated standards, or applies only a part of such standards, s/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 designated standards used to demonstrate conformity, or the technical specifications employed, if these are different from those in the designated 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 user information

All PPE placed on the market must be equipped with the Manufacturer's user information. The contents of such instructions are explained in clause 1.4 of Annex II Regulation 2016/425 on personal protective equipment as brought into UK law and amended. If designated standards are applied, these set out the amount of detail in the information to be given.

A copy of the Manufacturer's user information, clearly legible and easily understandable, must be included in the Technical Documentation, so that Certdolomiti can check its contents.

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 Regulation 2016/425 on personal protective equipment as brought into UK law and amended should not be confused with the risk assessment that an employer is required to make in relation to legislation regarding health and safety at work. The risk assessment defined in ~~as~~ Regulation 2016/425 on personal protective equipment as brought into UK law and amended concerns only PPE, and not working or use conditions.

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

a) Assessment of risk against which the PPE is intended 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 its 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 Regulation 2016/425 on personal protective equipment as brought into UK law and amended, the Technical Documentation could include, if the Client is preventively willing to communicate it, a declaration that identifies the approved 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 Regulation 2016/425 on personal protective equipment as brought into UK law and amended).

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 and risk assessment;
- 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 approved 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 t Regulation 2016/425 on personal protective equipment as brought into UK law and amended.

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. Liability

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

Certdolomiti to check the contents and comprehensiveness of the Technical Documentation and, where necessary, require an integration by the Manufacturer.

6 Quality Control registration

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