# TÜV Rheinland LGA Products – Information 01/2022

## PPE Regulation 2016/425 – Technical Documentation

Manufacturers and/or distributors of PPE (Personal Protective Equipment) should consider the specifications of the PPE Regulation 2016/425 early in the manufacturing process. Since the regulation came into force in April 2018, the requirements must be applied to all PPE products. The mandatory technical documentation, described in Annex III of the regulation, needs particular attention. It serves you as the proofs that your PPE complies with the essential health and safety requirements.

You are obliged to provide the authorities with the technical documentation on request, and this must be kept for 10 years following the placing of the PPE on the market. The technical documentation should, on request, be available in a language which can be easily understood by the competent national authorities (of the country in which the PPE is being distributed). In addition, the technical documentation helps us – i.e. TÜV Rheinland – as the notified body to verify that all the requirements of the Regulation have been met (conformity assessment).

The technical documentation should be compiled in a comprehensible form on business paper with a clear product reference and, if possible, as one file. Based on the criteria of the Regulation, as well as regularly asked questions, we would like to give you some guidance about how to put together the technical documentation for your PPE:

| | CONTENT | HOW? |
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| Product description<br>see: Regulation Annex III a) | A detailed, complete description is required, stating the area of application, the intended use and foreseeable use, the protection parameters (applicable standard), the materials, the weight per unit area, the colors and the claim concerning special features. | You can submit this information i.a.:<br>▪ by using our CDF (Construction data form) template as the basic document plus your amendments<br>▪ as a detailed instruction manual. |
| Risk assessment<br>see: Regulation Annex III b) | Your risk assessment must:<br>▪ specify the risk and the hazards against which the PPE is supposed to protect against (safety target),<br>▪ define the risk and the degree of severity of any possible threat to the user through the use of the PPE or through the PPE itself,<br>▪ explain the risk to the health and safety of persons other than the user,<br>▪ show the limits of the PPE's protective effect (residual risk),<br>▪ list the influencing factors which could possibly reduce the PPE's protective effect.<br>Hazards could arise through i.a. injuries due to physical effects or due to substances contained in the PPE that can cause health hazards. In addition, all measures should be consequently taken in order to eliminate or minimize the risks (if necessary, definition of warnings in the operating instructions or on the product, etc.). Therefore, the risk assessment should always be derived from the finished, tested and proven product – not, however, from the sum of the individual parts. | The Regulation does not specify any content-related or official data for compiling the risk assessment. It is up to the manufacturer to decide the form and the depth in which he prepares it. The risk assessment should be compiled in the form of an easily understandable technical documentation with an unambiguous product reference. |
| Health and safety requirements<br>see: Regulation Annex III c) | When developing and manufacturing a PPE, the basic health and safety requirements in Annex II of the PPE Regulation should be taken into consideration. | The Regulation specifies that a list with the relevant requirements (Annex II) should be compiled. |
| Design descriptions<br>see: Regulation Annex III d; e) | The regulation provides for production drawings, plans and explanations for comprehension at this point. | Depending on the complexity of the product, a detailed photo documentation of the sample might be sufficient. For complex products, such as, for example, protective clothing and protective footwear, we recommend that technical drawings be submitted clearly showing the various components which make up the PPE.<br>If the photo documentation and the technical drawings are not easy to understand, relevant explanations will have to be included. |

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| Reference of the harmonized standards – Official Journal of the EU<br>see: Regulation Annex III f) | A reference to the harmonized standards used as published in the Official Journal of the European Union is required. The EU Official Journal is updated and published once to twice a year. The manufacturer can assume that if harmonized standards are applied correctly in accordance with the published reference, the essential health and safety requirements according to the Regulation are fulfilled. | You quote the current harmonized standards, which are necessary to demonstrate that the PPE meets the requirements of the Regulation. This information can also be given in the CDF or the instruction manual. |
| Technical specification – test specifications<br>see: Regulation Annex III g) | For certain PPE products there are no harmonized standards or these can only be implemented in part. If necessary, the notified body can make a test specification for these products based on the requirements of the Regulation. | In this case, the parts of the standards implemented relating to the relevant points of the Regulation and/or the test specifications should be listed. |
| Test reports and proof of conformity<br>see: Regulation Annex III h); i) | The comprehensive technical documentation helps to prove the conformity. | This must be demonstrated based on the EU-type examination, e.g. through the information about which quality controls and/or material tests have been planned. The EU-type certificate also specifies the relevant protection class.<br>Test reports which were compiled during the EU-type examination, and, where relevant, also from the reports resulting from the internal manufacturing checks (Annex IV, Module A, number 3) must be submitted as evidence at the request of the authorities. |
| Quality management<br>see: Regulation Annex III j) | The manufacturer must outline the measures for self-monitoring the production process with which he ensures that the products from the current production are manufactured in accordance with the technical documentation and the relevant requirements of the Regulation. | For this purpose, information on the scheduled quality controls and/or planned material tests during and after manufacture must be provided and submitted to the authorities at any time upon request. |
| Instruction manual<br>see: Regulation Annex III k) | The instruction manual must contain all information required by the Regulation (Annex II, 1.4) and the standards applied. | A copy of the manual must accompany each of the smallest packaging unit of the PPE. |
| Customized PPE<br>see: Regulation Annex III l); m) | For a special PPE which is made to measure or customized, the manufacturer must still ensure that the necessary and applicable requirements of the PPE Regulation are met. | In this case all measures and instructions to be taken into consideration for the safe use of the customized PPE must be defined and described. |

In general, the economic operator must fulfil his obligations according to Regulation Chapter II. This also includes that the manufacturer and/or importer informs the notified body that carried out his EU type examination of all changes to the PPE or the technical documentation. Such changes may require additional approval in the form of a supplement to the original EU type certificate (see VO Annex V 7.2).

## You would like to have your PPE products tested and certified?

Contact our sales department:


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