At a glance.

The new PPE Regulation.

The new PPE Regulation 2016/425 took effect on April 20, 2016. The old PPE Directive 89/686 EEC for the testing and certification of personal protective equipment remains valid for another two years. During this period, TÜV Rheinland and the authorities have the time to prepare for the new requirements. Based on the new regulation, but also on our own activities in various boards and committees, we are providing you with information about the most important changes:

What do you need to know and what are the important dates?

The following dates are specified in the PPE Regulation 2016/425:

Taking effect

This regulation has taken effect on the twentieth day after its publication (03/31/2016) in the Gazette of the European Communities.

Date of Application *(Article 48)*

This regulation shall apply starting on April 21, 2018 with exception of

- Articles 20-36: Notification of Conformity Assessment Bodies, which shall apply from 10/21/2016
- Article 45, Par.1: Sanctions for Violations of the Regulation, which shall apply from 03/21/2018

Transitional provisions *(Article 47)*

- Products covered by the PPE Directive 89/686/EEC and that conform to that Directive and are made available on the market and are put into circulation before April 21, 2019 may continue to be sold.
- EC-type examination certificates and approvals issued under the Directive 89/686/EEC shall remain valid until April 21, 2023 unless they expire before that date.

Repeal

The Directive 89/686/EEC will be repealed with effect from April 21, 2018.

Supporting documents:

Currently, intensive work on the "interpretative documents" for the PPE Regulation is underway.

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What are the major changes from the previous PPE Directive?

- New legal structure: the Directive became a Regulation without leaving room for interpretation by national law. It also has a new structure: 48 Articles with 10 Annexes – now clear and understandable.
- Revised and expanded definitions for market players. As a result, the Regulation includes everyone in the supply chain and is a binding legislative act across the EU. The definition of the market players, previously "manufacturer" and "authorised representative", was expanded to include "distributor" and "importer".
- A re-categorisation of PPE products into three categories depending on the risk against which these products are protecting the user. Each of these categories has different testing requirements *(Art. 18 in connection with Annex I)*. Some types of PPE are classified in a different category than previously in the PPE Directive.
    - Examples for a re-classification in category III are PPE against:
        - Drowning (life vests)
        - Cutting injuries by hand-held chainsaws
        - High pressure jets
        - Bullet wounds or knife stabs
        - Harmful noise (hearing protection)
    - The scope of the Regulation has been extended to include "PPE for private use for protection against heat" (oven gloves).
    - Excluded from the PPE Regulation are seasonal clothing, umbrellas and dish-washing gloves for private use that protect against atmospheric conditions.
    - Also excluded from the Regulation are artisanal products for private use that have decorative purposes, as well as clothing with reflective or fluorescent components the main function of which is decorative.
- For each risk category there is a conformity assessment procedure by module *(Art. 19)*:
    - Module A: Internal production control (Cat. I).
    - Module B: EU-type examination (Cat. II, III).
    - Module C: Conformity to type based on internal production control (Cat. II).
    - Module C2 *(corresponds to Art. 11A of Directive)*: Module C + supervised product checks at random intervals (Cat. III).
    - Module D *(corresponds to Art. 11B of Directive)*: Conformity to type based on quality assurance of the production process + surveillance (Cat. III).
- This includes new definitions and adapted conformity assessment procedures for custom-made PPE that are produced in series or made to order (orthopaedic footwear).
- In the future, EU-type examination certificates will be valid for a maximum of five years.

- In the future, the declaration of conformity must accompany each individual PPE that is made available on the market. This requirement can be met by the manufacturer (or importer/distributor with PPE under their own name) by means of a "simplified declaration of conformity", which consists of only one single sentence and the reference to a website where the complete declaration of conformity can be found *(Art. 8)*.
- Regulations for market surveillance were incorporated in *Chapter VI*.
- Important Annexes at a glance:
  - Substantiated and expanded re-classification of risk categories *(Annex I).*
  - Amendment and revision of the most important health and safety requirements *(Annex II).*
  - Additional and detailed description of the required technical documentation *(Annex III).*
  - Minimum requirements in Modules A, B, C, D *(Annex IV - VII).*
  - Structural and contents-related information about the EU declaration of conformity *(Annex IX).*

Further information.

Please contact us if you have questions about the new PPE Regulation. We will be happy to assist you: service@de.tuv.com or phone + (0)341 6003690.

You may download the new PPE Regulation from the website of the European Union.

All information is without guarantee as to accuracy and completeness.