



## Leaflet. The new PPE-Regulation.

The new PPE-Regulation 2016/425 took effect on 20<sup>th</sup> April 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 time period both the economic operators, DIN CERTCO and the authorities have time to prepare for the new requirements. Based on the new regulation 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:

#### 1. Taking effect

This regulation has taken effect on the twentieth day after its publication (31<sup>st</sup> March 2016) in the Official Journal of the European Union.

#### 2. Date of Application

This regulation shall apply starting on 21<sup>st</sup> April 2018. Some articles have different dates of application. For example:

- Article 45, Par.1: Sanctions for Violations of the Regulation, which shall apply from 21<sup>st</sup> March 2018

#### 3. Transitional provisions

- Products which are covered by the PPE-Directive 89/686/EEC and made available on the market before 21<sup>st</sup> April 2019 can still be sold in order to reduce products in stock.
- EC-type examination certificates and approvals issued under the Directive 89/686/EEC shall remain valid until 21<sup>st</sup> April 2023 unless they expire before that date.

#### 4. Repeal

The Directive 89/686/EEC will be repealed with effect from 21<sup>st</sup> April 2018.

## 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.
- Revised and expanded definitions for all economic operators. Furthermore there are a lot of additional duties which are stated in chapter II of the regulation. Economic operators "manufacturer" and "authorized representative" are expanded with "distributor and "importer".
- A re-categorization of PPE products into three categories depending on the risk against which these products are protecting the user. 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)
- For each risk category there is a conformity assessment procedure by module.
- This includes new definitions and adapted conformity assessment procedures for custom-made PPE that are produced in series or made to order (orthopedic footwear).
- EU-type examination certificates will be valid for a maximum of five years.
- Additional requirements were made for the technical documentation and the EU-declaration of conformity was adapted.
- 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". This consists of only one single sentence and the reference to a website where the complete declaration of conformity can be found.
- Regulations for market surveillance were incorporated in.
- Amendment and revision of the most important health and safety requirements for PPE-products.

## Further information.

Please contact us if you have questions about the new PPE-Regulation. We will be happy to assist you: [christian.kampczyk@dincertco.de](mailto:christian.kampczyk@dincertco.de) or phone +49 911 6553022.

You may download the new PPE-Regulation from the website of the [European Union](#).