

# NEW PPE REGULATION (EU) 2016/425

For nearly 30 years, the PPE Directive 89/686/EEC has formed the framework for manufacturing and distributing PPE (personal protective equipment) in the European Union. For various reasons, the directive needed to be adapted, and in 2016 the new PPE Regulation (EU) 2016/425 was launched. This regulation becomes valid on April 21st, 2019.

## Most important changes

The new PPE Regulation (EU) 2016/425 is valid throughout the European Union as well as in the EEA EFTA states (Liechtenstein, Iceland, Norway), Switzerland and Turkey due to specific agreements. The new regulation incorporates the following major changes:

- ✓ Validity of EU type-examination certificates is now limited to 5 years. Therefore products are re-evaluated every five years and can be adapted in relation to changes in standards if needed. TEUFELBERGER has done this five-yearly re-evaluation voluntarily for several years.
- ✓ Marking and user instructions need to fulfill new requirements
- ✓ Roles and responsibilities of the market players (manufacturer, importer, distributor) are now defined more precisely

# Ready, set, GO

During the last year, TEUFELBERGER has been working hard to take all the necessary steps to fulfill the new PPE Regulation. Instructions for Use and product labels for more than 70 certified products have been reviewed and the process is now completed. All changes have been successfully implemented and we are ready to go! That's why you can always rely on TEUFELBERGER as your preferred PPE manufacturer.

# Responsibilities of distributors

In contrast to the old PPE Directive, the new PPE Regulation also defines the responsibilities and obligations for other market players like importers or distributors. As the manufacturer, we can't assume this responsibility for you, but we can advice you in the best possible way.

In order to fulfill the requirements of the new PPE Regulation (EU) 2016/425, you as a distributor of PPE need to ensure that

- ✓ PPE bears CE marking
- ✔ PPE is accompanied by Instructions for Use in the languages needed
- ✓ PPE is accompanied by a Declaration of Conformity (print or link)
- ✓ PPE is labeled correctly (including month/year of manufacture)
- ✔ PPE comes with the manufacturer's (and importer's) name and address

It is important for you to know that the distributor doesn't need to be in possession of all the documents, but needs to be able to identify the manufacturer/importer/distributor in order to ask for the documents in case they are not provided.

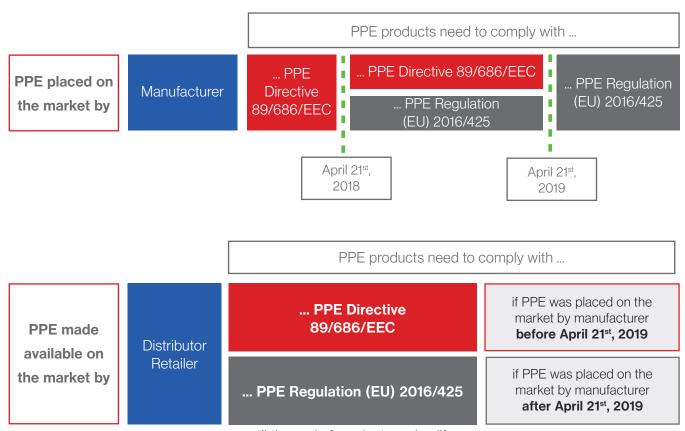
Please also note that based on the "Blue Guide" (rules valid for any EU regulation), distributors must be able to present information on suppliers or customers from or to whom products have been supplied for a period of 10 years.



### Overview and timing

The new PPE Regulation and its time schedule differentiate between the following concepts:

- ✓ Placing products on the market >> done by manufacturers
- ✓ Making products available on the market >> done by importers, distributors, retailers



until the end of product service life

In case of PPE products supplied by manufacturers after April 21st, 2019 which don't comply to the new PPE Regulation (EU) 2016/425, distributors and retailers are not allowed to make these products available to the market. These products need to be rejected until confirmity with the new PPE Regulation is guaranteed.

With TEUFELBERGER you can be sure that all products delivered after April 21st, 2019 are compliant with the new PPE Regulation (EU) 2016/425.

The entire PPE Regulation (EU) 2016/425 can be found here: https://eur-lex.europa.eu/eli/reg/2016/425/oj



# Important remarks regarding the new PPE Regulation



#### **CE Marking**

PPE products need to bear a CE marking. While it confirmed compliance with the PPE Directive 89/686/EEC in the past, it will confirm compliance with the PPE Regulation (EU) 2016/425 for PPE placed on the market as of April 21st, 2019



#### **Required documents**

PPE products need to be accompanied by required documents

- ✓ Instructions for Use
- ✓ Declaration of Conformity (DOC)

In the past, the Instructions for Use were obligatory but the DOC only had to be provided upon request.



#### Instructions for Use

Like in the past, PPE products need to be accompanied by printed Instructions for Use in a language which can be easily understood by end-users, as determined by the Member State(s) concerned. So in all likelihood these are the official languages of the country that the product is sold to.



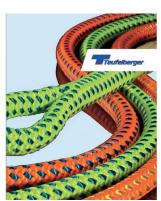
#### **Declaration of Conformity (DOC)**

PPE products need to be accompanied by the DOC. This can either be printed or the link can be added in the Instructions for Use. You can find the TEUFELBERGER DOC here:

https://www.teufelberger.com/en/downloads/declaration-of-conformity.html

In the past, the DOC only needed to be provided on request.





PERIODIC EXAMINATION AND REPAIR HISTORY				
Date	Reason for entry (Examination or Repair)	Defects	Name & Signa- ture of compe- tent person	

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604 Apport Road of Fiber May 16202
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PPE needs to come with the manufacturer's, and if applicable also the importer's, name and address. If space on the product is lacking, this data can also appear in the Instructions for Use or on the packaing.

In the past, only the manufacturer's data needed to be provided.



#### Labeling

As for the labeling requirements there are some general rules and some depend on the type of PPE (as before). However, there is a new rule that PPE subject to ageing (like textiles) needs to be marked with the month and year of manufacture.