

Regulation (EU) PPE 2016/425



1. Methods and timetable for application:

Regulation (EU) 2016/425 became effective on 20 April 2016 and has been in force since 21 April 2018. For the following year, however, the new legislation will coexist with Directive 89/686, **which will be definitively abolished on 21 April 2019**.

This means that during this transitional year, companies will be able to place on the market products that comply with the Directive or Regulation without distinction.

(Placing on the market refers to the first availability of PPEs on the European market = the moment when the goods are cleared through customs).

At the end of this transitional period, PPEs can only be introduced if they comply with the Regulation. **However, this does not mean that PPEs that meet the requirements of previous legislation will not be allowed to circulate on the market:**

Article 47(1) of the Regulation (EU) specifies that certifications of products placed on the market before 21 April 2019 and issued in accordance with the provisions of the Directive remain valid until 21 April 2023, unless they expire before. At the end of this period, it will be necessary to carry out a new certification in accordance with the Regulation.

All products already present in the distribution chain (i.e. already on the market, and therefore present in any EU warehouse, whether distributor, wholesaler or retailer), can be marketed until the natural expiry date of the PPE (if indicated) or the corresponding EC certificate and, if the certificate does not mention the expiry date, until the expiry date of 21/04/2023 (the latest expiry date of EC certificates under Directive 89/686/EEC).

We remind you that according to the new Regulation, end-users are not considered as economic operators and can therefore continue to use PPEs certified according to the old Directive 89/686 EEC even after this date (21/04/2023) and until the device expires if and where the manufacturer indicates it.

2. Main new features of the Regulation compared to the repealed Directive:

- The classification of PPEs is now based on risk categories and no longer on products;
- The classification of certain product categories has been modified;

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- Hearing protection, now classified as (risk of) "harmful noise", will be moved from category II to category III;
- Each product must be accompanied by the EU declaration of conformity (or a link to the page where this declaration is available);
- The technical documentation and the EU declaration of conformity must be kept for a period of 10 years from the date on which the PPE is placed on the market;
- Newly issued certificates have a validity period/expiry date of 5 years;
- The obligations of economic operators in the supply and distribution chain have been described.

HERE ARE THE MOST COMMON QUESTIONS AND ANSWERS ABOUT THE TRANSITION PERIOD OF THE REGULATION:

D. I am an end-user: with the new European regulation 2016/425, how long can I continue to use PPEs certified according to the old EEC directive 89/686?

A: PPEs purchased and certified under the old EEC Directive 89/686 can continue to be used until the natural expiry date of the device if and where indicated by the manufacturer.

D. I am a distributor: with the new European regulation 2016/425, how long can I continue to sell PPEs certified according to the old EEC directive 89/686?

A: To answer this question, it is necessary to emphasise these two definitions:

- "made available on the market": the supply of PPEs for distribution or use on the EU market in the course of a commercial activity (distributors)
- "Placing on the market" means the placing on the market the first making available of a PPE on the EU market (manufacturers and importers)

At this stage, we can say that all PPEs conforming to the old EEC Directive 89/686 "placed on the market" (i.e. cleared through customs) before 21 April 2019 can be made available until the natural expiry of the device if and where indicated by the manufacturer (i.e. no later than 21 April 2023).

*This disclosure has been prepared by Industrial Starter S.p.A. on the basis of the communications available at the time of publication and it is only an aid to knowledge of certain aspects related to the new Regulation (EU) 2016/425. It should therefore not be considered as an exhaustive document on the content of the Regulation itself.