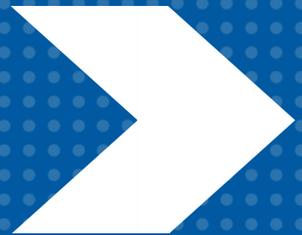


New EU Regulation for Personal Protective Equipment: what does it mean for European SMEs?

As of 21 April 2018, the provisions of the new Regulation (EU) 2016/425 apply to manufacturers, importers, distributors and reprocessors of personal protective equipment (PPE). The aim of the EU PPE Regulation is to:

- Lay down requirements for the design and manufacture of PPE ;
- Ensure the health and safety of users, domestic animals and property;
- Allow the equipment to be sold and used throughout the European Union.



What happens to the old PPE Directive?

After almost 30 years from its entry into force, the PPE Directive 89/686/EEC is repealed by the new Regulation. This does not mean that products which are in conformity with the old Directive can no longer be made available on the market. On the contrary, the agreed one-year transition period will guarantee the marketing of these products until 20 April 2019. The presumption of conformity under the old PPE Directive will cease then.

As a manufacturer, does this mean that I must retest all my products?

No. Certificates and approval decisions issued under the PPE Directive, before 21 April 2019, remain valid also for providers and suppliers (e.g. laundries, rental companies, dealers, textile services) until 21 April 2023 unless they expire before that date.

Then, test reports will continue to be valid if the manufacturer has not modified the product or the tested part used in the PPE, or the reference standards have not changed in a way that potentially affects the conformity of the product. Nevertheless, products that are put on the EU market after 21 April 2019 must have a new EU-type examination certificate (from the Notified Body) if they are category II or III and a new declaration of conformity (from the manufacturer).

Does anything change for importers and distributors of PPE?

Yes. Under the new regulatory framework, they have the same responsibilities as manufacturers. This means that they need to ensure that the product complies with the Regulation and keep the technical file and records.

If anybody in the supply-chain changes the product in a way that changes its conformity with the legislation, the EU-Type approval becomes invalid and that person becomes the manufacturer with all their responsibilities.

In which way are reprocessors of PPE (e.g. renting companies, industrial textile services) affected?

With the introduction of the new Regulation, reprocessors of PPE can rely on clearer information. Indeed, manufacturers are asked to provide information and documentation about a number of criteria that will help reprocessors in their work. Among these, information to determine a reasonable period of obsolescence, maximum number of cleaning cycles that can be performed, laundering conditions (i.e. domestic and/or industrial laundry process and temperature), etc.

This flyer was edited by Small Business Standards (SBS), the association supporting European SMEs in standardisation.



Any questions?
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