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Personal Protective Equipment Directive Update April 2018

As manufacturers of personal protective equipment for use in high hazard working environments, Tilsatec understand the importance of ensuring our customers and partners are fully aware of significant changes and updates relating to industry standards and legislation.

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On February 12th 2016 the new **PPE Regulation (EU) 2016/425** was finalised and will be formally adopted as of April 21st 2018. There will however, be a one year transition period until April 2019.

This leaflet provides an overview of the key changes and a time line of when you can expect to see these taking effect.

Why the need for change?

- The PPE Directive is now over 20 years old
- It needs to reflect new technologies and developments in product design
- Current Directive is only applicable to EU Member States, the new Regulation will apply to all EU citizens
- It is currently transposed into each Member State's national law and therefore governed by each country differently
- The new Regulation is a binding legislative act applied in its entirety across the EU

What are the main changes?

- Bespoke items of PPE are now included in the directive
- An EC Declaration of Conformity must be made available with every item of PPE or a link provided to where it can be obtained
- Manufacturers are required to put their name and address on the item of PPE (with the exception of gloves due to size of product) and also within the EC DOC
- The responsibilities of both manufacturers and importers are clearly outlined
- A copy of the product risk assessment must be included with the technical file submitted for certification
- An EU examination certificate will be issued with a compulsory five year validity. If the item of PPE does not change, manufacturers will only be required to re-certify products up to 12 months before the expiry date of the certificate.

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The new directive applies not just to manufacturers, but importers, distributors and everyone involved in the supply of PPE. Manufacturers need to ensure all product certification is kept up to date and distributors and resellers need to ensure the product they are placing on the market is fully compliant.

The new directive specifies three classes of PPE based on the following categories of risk:

Category I: Simple PPE

Gloves and sleeves designed to protect against minimal risks such as superficial mechanical injury and cleaning.
Manufacturers are permitted to test and self certify products.

Category II: Intermediate PPE

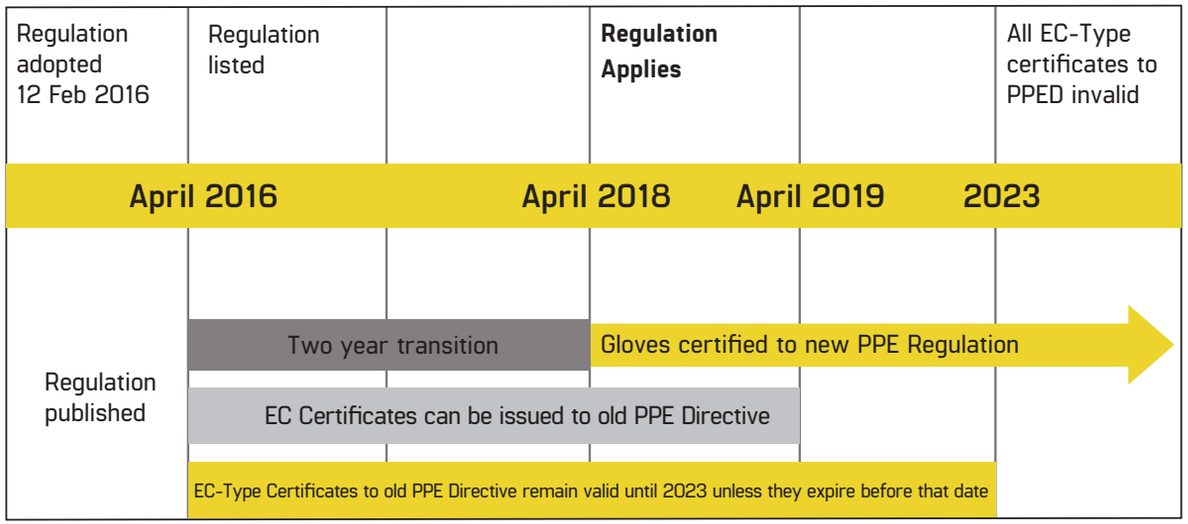
Hand and arm protection designed to protect against cuts, abrasion, puncture and tearing.
This category of products must undergo independent testing and attain certification by an accredited notified body. A CE mark will then be issued by the notified body. No item of PPE can be sold or used in the EU without being issued a CE mark.
The name and address of the notified body that issued the CE mark, must be present on the Instructions for Use supplied with the product.
Ongoing surveillance of performance must be carried out through testing.

Category III: Complex PPE

PPE in this category includes risks that may cause very serious consequences such as death or irreversible damage to health e.g. chemicals, harmful biological agents, extreme temperatures and cuts by hand-held chainsaws.
PPE must undergo independent testing and certification the same as Category II products. The quality assurance system used by the manufacturer must also be independently checked and the identification number of the notified body should appear alongside the CE mark on the Instructions for Use.
Ongoing surveillance of performance and manufacturing processes must be carried out through product testing and conducting factory audits.

Time line of key dates for regulation transition

Between April 2018 and April 2019 manufacturers can supply products within the EU certified to both the Directive and the Regulation. From April 2019 new products can only be placed on the market certified to the new Regulation.



For further guidance or if you have any questions on the new PPE Regulation you can contact our Commercial & PPE Manager, Ben Griffiths email: ben.griffiths@tilsatec.com.
More information can also be found in "The PPE Directive and the PPE Regulation" whitepaper issued by the **British Safety Industry**: *https://www.bsigroup.com/Documents/BSI-PPE-Whitepaper-UK-EN.pdf*