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Guide to the Personal Protective Equipment (PPE) Regulation (EU) 2016/425

As of April 2018, the new Personal Protective Equipment (PPE) Regulation 2016/425 repeals the PPE Directive 89/686/EEC. The new regulation has been introduced to harmonise processes and reflect current practice for developing and bringing PPE to the market in Europe.

The PPE Regulation is a binding legislative act and imposes clear and detailed requirements which must be applied in their entirety across the EU member states. The regulation applies to all forms of PPE supply, including distance selling, and seeks to establish high levels of health and safety practice, protection of users, and fair competition.

There are several principle changes which are:

- Change of categorisation from product related to risk related
- Change of classification for certain product categories
  - Hearing protection, now categorised as 'harmful noise' (risk) is moving from Category II to Category III
- EU Declaration of Conformity to be provided with each product (or a link to where it can be obtained)
- Technical documentation and the EU declaration of conformity held for 10 years after the PPE has been placed on the market
- 5-year validity / expiry date for new certificates
- Outlined obligations for economic operators within the supply and distribution chain

Obligations of economic operators

(Economic operator – everyone intervening in the supply chain; manufacturers, authorised representatives, importers and distributors)

- Place only compliant PPE on the market
- Ensure that the PPE is accompanied by the instructions and information in a language which can be easily understood by consumers and other end-users
- Ensure that storage or transport conditions do not jeopardise the PPE's conformity
- Take corrective action in case of product non-conformity
- Co-operate with authorities as required

In addition to the economic operator obligations the manufacturer, importer and distributor must comply with the following:

Obligations of manufacturers

- Design and manufacture PPE products in accordance with the applicable essential health and safety requirements
- Ensure compliance to requirements of the PPE Regulation when placing products on the market after April 2019
- All Category II and Category III products to be re-approved every 5 years
- Provide the EU declaration of conformity with the PPE or a link to where it can be obtained
- Keep the technical documentation and the EU declaration for a minimum of 10 years after the PPE has been placed on the market
- Mark all PPE products with the correct markings and postal address (where this is not possible, on its packaging or in a document accompanying the PPE)

Obligations of importers

- Before placing PPE on the market, importers shall ensure that:
  - The appropriate conformity assessment procedure has been carried out by the manufacturer
  - The PPE bears the CE marking and is accompanied by the required documents
- Importers shall indicate, on the PPE, their name, registered trade name or registered trade mark and their postal address
- Where the importer considers or has reason to believe that the PPE is not in conformity, they shall not place it on the market and shall inform the manufacturer and market surveillance authorities
- Keep a copy of the EU declaration of conformity for a minimum of 10 years after the PPE has been placed on the market

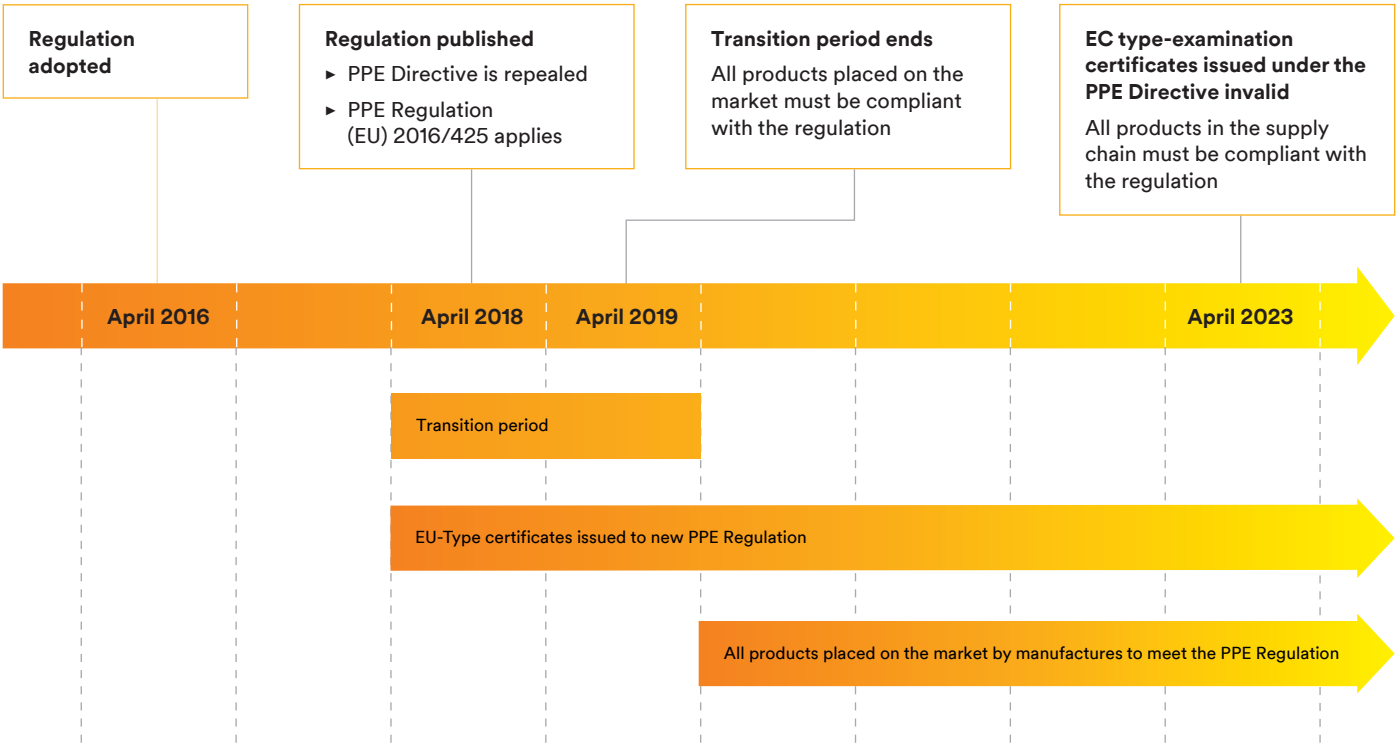
Obligations of distributors

- Before making PPE available on the market, distributors shall verify that:
  - The PPE bears the CE marking
  - The PPE is accompanied by the required documents and instructions in a language which can be easily understood by consumers and other end-users
  - The manufacturer and the importer have complied with the requirements
- Where the distributor considers or has reason to believe that the PPE is not in conformity, they shall withdraw or recall the product and shall inform the manufacturer and market surveillance authorities

Recommendations for the PPE user

- When appropriate, request documentation showing compliance to the Regulation from your PPE supplier
- Train workers in the correct selection and use of PPE
- Ensure all PPE is properly maintained and used for its intended purpose

Timeline for the regulation



Resources

For further information on the re-categorisation of harmful noise from Category II to Category III please refer to:

https://www.3M.co.uk/3M/en_GB/worker-health-safety-uk/safety-solutions/harmful-noise-regulation/

Declarations of conformity and EU certificates

Declarations of Conformity and EU certificates for 3M products can be located by the links below:

Respiratory Products Certificate Selector:
www.3M.com/Respiratory/certs

Welding Products Certificate Selector:
www.3M.com/Welding/certs

Fall Protection Products Certificate Selector:
www.3M.com/FallProtection/DOC

PELTOR Communication Products Certificate Selector
http://www.3M.com/Peltor/DOC

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