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PPE REGULATION (EU) 2016/425 - SUMMARY SHEET



ECONOMICAL OPERATOR **Manufacturer**

Directive 89/686/EEC
Current status


Regulation (EU) 2016/425
As of April 2019

Responsibilities:

Under the Directive, the manufacturer needed to ensure the products get certified, including:

- Not make PPE available in the market if the PPE is considered unable to meet the essential health and safety requirements
- Ensure the CE mark, the correct markings/claims, the IFU and the EU declaration of conformity "EU DoC" is available

Responsibilities / Changes:

- Ensure that the PPE is safe and safe for the intended purpose and compliant
- Have procedures in place for series production to remain in conformity with the PPE Regulation
- Take corrective actions in case of non compliance and inform the competent authorities where PPE presents a risk
- Cooperate with authorities in a language which can be easily understood by that authority
- Indicate on the PPE or packaging their name and single point postal address
- Ensure PPE bears a type, batch or serial number  MMYYYY
- Carry out the conformity assessment, apply the CE mark and draw up the EU declaration of conformity "EU DoC"
- Keep technical file + EU DoC available for 10 years after PPE is placed on the market
- Ensure the PPE is accompanied with the Instructions for Use "IfU" and provide the EU DoC with the PPE or add the internet address to the IfU where the EU DoC can be accessed
- Inform the competent authorities where PPE presents a risk
- Where needed, carry out sample testing
- Ensure that transport and storage does not jeopardize the PPE's conformity



ECONOMICAL OPERATOR

Importer

Directive 89/686/EEC
Current status

Regulation (EU) 2016/425
As of April 2019

Responsibilities:	Responsibilities / Changes:
No requirements defined	<ul style="list-style-type: none"> Place only compliant PPE on the market Inform the competent authorities where PPE presents a risk Cooperate with authorities in a language which can be easily understood by that authority Not make PPE available in the market if the PPE is considered not to meet the essential health safety requirements and, where needed, carry out sample testing Ensure that transport and storage does not jeopardize the PPE's conformity Indicate on the PPE or packaging their name and postal address (if manufacturer is outside EU) Shall ensure the conformity assessment is carried out, the CE mark, the correct markings/claims and the EU declaration of conformity "EU DoC" is available Shall ensure the PPE is accompanied with the Instructions for Use "IfU"



ECONOMICAL OPERATOR

Distributor

Directive 89/686/EEC
Current status

Regulation (EU) 2016/425
As of April 2019

Responsibilities:	Responsibilities / Changes:
No requirements defined	<ul style="list-style-type: none"> Act with due care and verify that the PPE bears the correct markings and is accompanied by the required documents in a language that can be easily understood by the consumers Not make PPE available in the market if the PPE is considered not to meet the essential health and safety requirements Ensure that transport and storage does not jeopardize the PPE's conformity Take corrective actions in case PPE is considered to be non compliant and inform the competent authorities in case PPE presents a risk, hence the "traceability requirement" Cooperate with authorities and provide all the information necessary to demonstrate compliance Become responsible if they make alterations to incoming products

For more information on this new Regulation and about future PPE Regulation updates visit:

www.ansell.com/enresourcecenter