



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

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Version 2

RECOMMENDATION FOR USE

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Origin : Horizontal Committee	<input type="checkbox"/> Vertical Group	30/05/2018	
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Question related to	<input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> Other:
Article:	Annex: Annex III, b), Annex V, 2	Clause:	
Key words:			
Risk assessment			
Question:			
What is required by the manufacturer and the notified body as far as risk assessment is concerned?			
Solution:			
The adequate analysis and assessment of the risk(s) is the responsibility of the manufacturer.			
The manufacturer describes the identified risks and shows the related sections of standards / specification plus the associated assessment method, e.g. analysis, inspection, test.			
The notified body reviews the documentation to ensure that			
<ul style="list-style-type: none">– the risks are correctly identified with respect to the application made and the PPE presented– the submitted user information reflects the identified risks and includes associated limitations of use as far as the requirements of the PPE Regulation are concerned.			