



CO-ORDINATION OF NOTIFIED BODIES  
PPE Regulation 2016/425

PPE-R/00.061  
Version 1

RECOMMENDATION FOR USE

Number of pages: 1	Approval stage :	Approved on :	
Origin : Horizontal Committee	<input type="checkbox"/> Vertical Group	30/05/2018	
	<input checked="" type="checkbox"/> Horizontal Committee		
	<input type="checkbox"/> EU PPE Working Group		
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"><li>– the risks are correctly identified with respect to the application made and the PPE presented</li><li>– 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.</li></ul>			