



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/00.038
Version 1

RECOMMENDATION FOR USE

Number of pages: 1	Approval stage :	Approved on :
Origin : Horizontal Committee	<input type="checkbox"/> Vertical Group	12/06/2017
	<input checked="" type="checkbox"/> Horizontal Committee	23/01/2018
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Question related to <input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> Other:
Article: Annex: II, 1.2.1.1	Clause:	
Key words: innocuousness of PPE		
Question: What should notified bodies require from the manufacturer to demonstrate compliance with annex II, 1.2.1.1 ?		
Solution: Compliance may be demonstrated by a written declaration confirming that the submitted PPE does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health, if present; a list of these substances has to be submitted as part of the technical file. Tests as required by harmonised standards will not be affected.		