



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/00.036
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		
	<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: 25	Annex:	Clause:	
Key words: harmonised standards, essential requirements, EU type-examination			
Question: When carrying out an EU type-examination, what is the responsibility of the notified body when the applicable harmonised product standard does not address all the relevant essential health and safety requirements?			
Solution: Where a relevant harmonised product standard does not address all the relevant essential health and safety requirements the manufacturer must identify those not addressed in the standard and also state how these are dealt with in his technical documentation. The notified body is responsible for confirming that all the relevant essential health and safety requirements have been identified, listed and adequately dealt with when carrying out their review, inspection and testing for the EU type-examination. Note 1: A harmonised product standard gives a presumption of conformity with those essential health and safety requirements which it identifies for the product and addresses. Note 2: It must be remembered that the Regulation is the law and must be complied with whilst standards are one means by which a manufacturer may demonstrate his compliance with the Regulation's requirements.			