



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/00.014
Version 1

RECOMMENDATION FOR USE

Number of pages: 1		Approval stage :	Approved on :
Origin : Horizontal Committee		<input type="checkbox"/> Vertical Group	n/a
		<input checked="" type="checkbox"/> Horizontal Committee	30/03/2017
		<input checked="" type="checkbox"/> EU PPE Working Group	23/01/2018
Question related to	<input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> Other:
Article:	Annex: VIII	Clause:	
	Module D		
Key words: Module D: Suspension, withdrawal or restriction of certificates			
Question: What procedure should be followed in the event of failures during module D assessments?			
Solution: In the event of failures during module D assessments, the notified body concerned has to decide in each individual case, taking into account the reasons that lead to the failure and the risks involved. In serious cases, e.g., major nonconformities issued against either the system or the product, the notified body should decide to either restrict, suspend or withdraw their module D approval; in that case other notified bodies and the Member State giving notification will have to be informed. NOTE: The failures can concern both quality system failures and product performance failures. In the case of product failures, the module B notified body shall be informed.			