



**CO-ORDINATION OF NOTIFIED BODIES**  
**PPE Regulation 2016/425**

PPE-R/00.016  
Version 4

**RECOMMENDATION FOR USE**

Number of pages: 1	Approval stage :	Approved on :
Origin : C2D Ad hoc group	<input type="checkbox"/> Vertical Group	n/a
	<input checked="" type="checkbox"/> Horizontal Committee	2019.07.18
	<input type="checkbox"/> EU PPE Working Group	
Question related to	<input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> PPE Guidelines
	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> Other:
Article:	Annex: VIII	Clause:
	Module D	
Key words: Re-assessment of approved quality systems		
Question: Shall approved quality systems be re-assessed?		
Solution: Yes, at a maximum frequency of every fifth year, with surveillance audits being carried out once per 12 month period following issue of approval. Each surveillance audit shall review any significant changes that have taken place, or are planned to take place, to determine if a reassessment is required before the due date.		
NOTE: This revision recognises that there is a range of different routes to notification and not all require that the principles of ISO17021 are followed. In addition, the PPE Regulation has a maximum validity for module B certificates of 5 years and the same approach is considered acceptable and reasonable for module D approvals.		