

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE		PPE-R/00.008 Version: 5 20/05/2026 Language: E
Number of pages: 2		Approval stage: Approved on:	
Origin: Horizontal Committee		☐ Vertical Group ☒ Horizontal Committee ☐ EU PPE Expert Group	
Question related to ☒ PPE Regulation		☐ EN/prEN: ☒ Other:	
Article: Annex: VII Module C2		Clause:	
Key words: Standard template for report content covering annual assessment process			
Question: What are the minimum requirements for a Module C2 report content? NOTE: PPER clearly specifies that 2 separate activities are required when assessing module C2, namely: - 1) Annual selection of samples to confirm compliance with the reference standard / specification and the type-examined AND 2) Annual selection of samples to gather evidence of homogeneity.			
Solution: See attached pages 2 and 3			

Module C2 Annual Surveillance Report

Notified Body – name / address / number:

Certificate holder:

Period covered by report:

General Reference Documents:

PPE Regulation 2016/425/EU, Module C2 EU type-examination certificate numbers covered by the surveillance:

Harmonised standards / technical specifications within the scope of the surveillance:

A. Annual assessment of product compliance with standard / specification and type-examined

1. Location(s) visited and dates:

2a. Selection carried out by..... Relationship to notified body.....

2b. Company representative, name and position..... 2c.

Relationship of company visited to type-examination certificate holder

Certificate Holder	Production site	Importer	Secondary production site
Distributor	Retail Outlet	European office of same company	
Other (please specify)			

List of PPE

- available
- not available
- not selected
- selected plus lot / batch numbers

3. Attached reference documents

Visit report, number xxxxxxxx Test report, number yyyyyyy

4. Sample selection was positive / negative. Product testing was positive / negative

5. Sample selection and testing demonstrated compliance with the reference specification / standard and type-examined, yes / no.

B. Annual assessment of production not being homogeneous

1. Method employed to perform assessment, please specify:

- On-site review of production and test records.
- On-site audit of production control.
- Production non-homogeneity assessed by selection of a single, large sample.
- Production non-homogeneity assessed by assessment of samples throughout the year.

2a. Assessment(s) carried by Relationship to notified body.

2b. Company representative, name and position.....

**Confidential
date:**

Report number and

Module C2 Annual Surveillance Report

3. Attached reference documents.

Visit report(s), number xxxxxxxx

Test report(s), number yyyyyyyy

4. According to our judgement, the assessment concluded that production was not homogeneous, yes / no.

Justification of

nonconformities Conclusion

of notified body:

Overall conclusion of the annual surveillance, positive / negative.

Signature..... Name and position Date

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