



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425

PPE-R/00.008
Version 1

RECOMMENDATION FOR USE

Number of pages: 3	Approval stage :	Approved on :	
Origin : Horizontal Committee	<input type="checkbox"/> Vertical Group	n/a	
	<input checked="" type="checkbox"/> Horizontal Committee	30/03/2017	
	<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:	Annex: VII	Clause:	
	Module C2		
Key words: Standard template for report content covering annual assessment process			
Question: What are the minimum requirements for the report content when implementing Recommendation for Use sheet 00.007? NOTE: Sheet 007 clearly specifies that 2 separate activities are required when assessing module C2, namely: - 1) Annual selection of samples to confirm continued compliance with the reference standard / specification and the type-examined AND 2) Annual assessment of the production control to determine any evidence of non-homogeneity.			
Solution: See attached pages 2 and 3			

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Report number and date:

Module C2 Annual Surveillance Report

Notified Body – name / address / number:

Certificate holder:

Period covered by report:

General Reference Documents:

Recommendation for use sheet, 007.

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, reference 2A of sheet 007

1. Location(s) visited and dates:

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

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

3. 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

4. Attached reference documents

Visit report, number xxxxxxx Test report, number yyyyyyy

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

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

B. Annual assessment of production not being homogeneous, reference 2B of sheet 007

1. Method employed to perform assessment, please specify:

2B(i) - On-site review of production and test records.
 2B(ii) - On-site audit of production control.
 2B(iii) - Production non-homogeneity assessed by selection of a single, large sample.
 2B(iv) - 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.....

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Report number and date:

Module C2 Annual Surveillance Report

3. Attached reference documents.

Visit report(s), number xxxxxxx Test report(s), number yyyyyyy

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