	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.008 Version 2

Number of pages: 3	Approval stage : Approved on :
Origin : Horizontal Committee	☐ Vertical Group n/a ☒ Horizontal Committee 30/05/2018 ☐ EU PPE Working 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 the report content when implementing Recommendation for Use sheet 00.007?

NOTE:

RfU 00.007 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

Confidential **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, 00.007. 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 RfU 00.007

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 xxxxxxx **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, reference 2B of RfU 00.007

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……

Confidential **Report number and date:**

Module C2 Annual Surveillance Report

3. Attached reference documents.

Visit report(s), number xxxxxxx 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 ……..