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Article:	Annex: VII Module C2	Clause:	

Key words:

Conformity to type, product checks, module C2

Question:

What is the correct interpretation of the requirements of module C2?

Solution:

See attached.

Module C2 interpretation. (*Text from Regulation is in italics*)

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS

1.
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of the Regulation.

2.
2.1 The notified body shall carry out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.

2.2 An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.

2.3 The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.

2.4 If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.

The product checks shall include both 2A and 2B: -

2 A.

Selection of product samples by the notified body or an independent representative of the body. Selection shall be made at a location agreed between the notified body and manufacturer. (2.2)

The samples shall be randomly selected from available stock, be representative of the certified range and sufficient samples taken to enable the required testing to be carried out. The samples shall be examined by the notified body to confirm that the manufactured PPE is as type-examined and remain in conformity with the standard or specification referenced on the corresponding valid type-examination certificate. (2.2)

AND

2B.

The notified body shall identify any instances of production not being homogeneous (2.4) by one of the following:

(i). Once per year, carry out on-site review of company production and test records. Review to take place where at least the final assembly of PPE is carried out.

(ii). Once per year, carry out an on-site audit of the production control. Audit to take place where at least the final assembly of PPE is carried out.

(iii). Once per year, take sufficient samples to evaluate production non-homogeneity.

(iv). Submission of samples throughout the year, each sample smaller in size than in (iii), based upon production information supplied by the manufacturer, to evaluate production non-homogeneity.

The test chosen under 2B (iii) and (iv) to evaluate non-homogeneity to be a simple, straightforward, objective test, directly related to the performance of the product.

Evidence of non-homogeneity to be in the terms of conformity with the PPE Regulation, essentially all results to be in conformity with the applicable specification / standard. No measurement of deviation, spread of results, trends etc.

3.
Where the notified body referred to in point 2 is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.

4.
If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.

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5.1 The notified body shall provide the manufacturer with a test report.

5.2 The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.

Note: Appropriate tests performed by the manufacturer may not be as specified in the standard. Where this is the case, evidence of correlation must be available.