

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.007 Version 5 20/05/2026
Number of pages: 4	Approval stage : Approved on :	
Origin : Horizontal Committee – sub-group Ad-Hoc C2 / D	☐ Vertical Group ☒ Horizontal Committee ☐ EU PPE Expert Group n/a 20/05/2026	
Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:		
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?		
Solutions: See attached pages.		

Module C2 interpretation. (*Text from Regulation is in italics*)**CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS****Annex VII, 1.**

Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 5.2 and 6, and ensures and declares on his sole responsibility that the PPE, which has been subject to the provisions of point 4, is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

'Subject to' means under a legally enforceable agreement with a Notified Body for Module C2 services, and where the Manufacturer is in possession of a valid Module B certificate.

'in conformity with the type' means, following implementation of an internal production control system, the manufacturer has produced and marked PPE and on their sole responsibility deem it to be compliant to the Module B and the approved type.

Annex VII, 2. Manufacturing

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.

As in Annex VII, 1 – the responsibility for conformity remains with the manufacturer, and as such accepts all risk when placing goods on the market.

Annex VII, 4. Product Checks, 4.1

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.

'Product checks' is inclusive of testing within a laboratory independent of the manufacturer, as well as visual checks of marking and other documentation supplied with the PPE.

'Homogeneity' is to be a consideration of the 'likeness' of each PPE tested from actual production (not those prepared for the NB Product checks) with that of the original type-examination testing, as separated by one or more production variables (e.g. time, shift, batches, lots, production runs, personnel, competence etc.) or storage variables (e.g. conditions, duration, etc.), following independent laboratory testing and other visual checks.

'Conformity' is to be a consideration of the ability of a selection of PPE from actual production (not those prepared for the NB Product checks), to meet the performance requirements as identified in the standard(s) / technical specification(s) applied by the manufacturer, and achieved within the Module B type-examination, following independent laboratory testing and other visual checks.

Annex VII, 4. Product Checks, 4.2

The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The first product checks shall be carried out no more than one year after the date of issue of the EU type-examination certificate.

'Random intervals' is to be understood as from periods of production chosen by the notified body, i.e. the manufacturer cannot tell the notified body from which production items the notified body shall sample. To facilitate a sampling visit, this may necessitate informing a manufacturer of the period in which you intend to visit.

Annex VII, 4. Product Checks, 4.3

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.

'Adequate statistical sample' is to be understood in the context of 'homogeneity', as defined above, and not an adequate statistical sample of all of production within the annual period – as such measures would be prohibitively destructive / expensive. The results produced for homogeneity must permit i) comparison of alike things (i.e. Production items where production variables are kept to a minimum), and ii) comparison of possibly unlike things (i.e. Production items where production variables differ considerably). For example, sample three or more from each batch chosen (i, sub-sample), but then from a minimum of 3 batches (ii, sample). It is not always possible to do statistical analysis of the sampled results, as many standards contain PASS/FAIL results.

For conformity purposes, sufficient samples must be taken to repeat type-examination testing to produce data to compare to original type-examination data, following consideration of the informed VG positions on conformity testing for Module C2 purposes

Annex VII, 4. Product Checks, 4.4

Where the notified body referred to in point 3 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.

'Difficulties' may be interpreted as failures on behalf of the manufacturer to permit sampling, refusal to undertake product checks, nonconformities identified during product checks, or other factors that delay or inhibit the delivery of the Module C2 service. It may also include uncertainty over or clarification requests concerning the Module B technical documentation or certification.

Annex VII, 4. Product Checks, 4.5

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.

'Sampling procedure' should consider the numbers as described above in 'adequate statistical sample', but also the practicality of sampling and recording of production variables.

'Acceptance' in the context of a sampling procedure ensures that it is the notified body that determines which samples are to form part of the Product Checks. It should factor in the ability to obtain homogeneity and conformity samples, and what data is recorded for traceability of those samples to production records.

'Within acceptable limits' in this context shall be comparable to that needed to achieve a performance class or level, or the manufacturer's claimed performance as per the type-examination and technical documentation.

Annex VII, 4. Product Checks, 4.6

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.

'not homogeneous' is to be explored in consideration of 'within acceptable limits' above. For example, a fabric sample which resists flame for 30 seconds compared to a sample which resists flame for 130 seconds are not homogeneous, but both would comply with ISO 15025 and a 10 second exposure time. If results produce show a spread, but are in conformity with the type-examination and do not introduce new risks to the user – appropriate measures are to bring it to the attention of the manufacturer as a concern not preventing continued certification.

Where PPE does not comply with the type described, actions guided by Chapter VI 'safeguard procedure' shall be followed, with reduction, suspension and withdrawal of certification as necessary.

The following procedure concerns the typical scenario, and does not take into account inability to physically attend to sample, where no production has occurred within the first 12 months of the Module B, nor where no production has occurred in the current year of product checks.

Typical procedural requirements applying the above

- a) Selection of product samples is to be undertaken by the notified body or an independent representative of the body. Independence may mean anonymous person purchasing from a website. Caution must be taken to ensure that it is not old stock.
- b) Selection shall be made at a location agreed between the notified body and manufacturer. Which may include purchase online, from the OEM, or another economic operator.

The samples shall be randomly selected from available stock (e.g. not presented for collection by the manufacturer), be representative of the certified type and sufficient samples taken to enable the required testing to be carried out. Where several type share characteristics which permitted a reduction in type-examination testing (e.g. a common fabric), overall sampling may be of various type provided this is reflected in test plans (e.g. considering a product range).

Sampling examples:

- (i) - Once per year, take sufficient samples to evaluate production non-homogeneity.
 - (ii) - Collection of samples throughout the year, each sample smaller in size than in (i), based upon production information supplied by the manufacturer, to evaluate production non-homogeneity.
- c) The samples shall be examined by the notified body, or an independent laboratory or person under the responsibility of the notified body.
 - d) Conformity of test results shall be confirmed by all test results conducted to the standard(s) / technical specification(s) of the type-examination achieving equivalent performance.
 - e) Conformity of inspection results shall be judged by comparing the sampled information to the Module B instructions, warnings, and marking information.
 - f) Homogeneity of test results shall be confirmed by all test results conducted to a quantitative method from the standard(s) / technical specification(s), or by that developed in the applicable VG, meeting both the (e) conformity confirmation, and having a variation in measured result that is not known or suspected to bring the PPE out of compliance, or introduce new risks to the user.

Other options include:

- (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 Product Check of the production control. Check to take place where at least the final assembly of PPE is carried out.
- g) The test chosen under f) to evaluate homogeneity are to be a simple, straightforward, objective test, directly related to the performance of the product.
- h) 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 as noted within the type-examination certificate and associated technical documentation. Any measurement of deviation, spread of results, trends etc should be communicated to the manufacturer, but no action is required of them where there is no product safety concern.
- i) Homogeneity of inspection results shall be confirmed by all samples matching visually (e.g. colour, size, construction).