

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/00.083 Version 01 11/05/2026
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Origin : Horizontal Committee – sub-group Ad-Hoc C2 / D	☐ Vertical Group n/a ☒ Horizontal Committee 20/05/2026 ☐ EU PPE Expert Group	
Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:		
Article: Annex: VII Clause:		
Key words:		
New Type; Extension to Module C2		
Question: What actions must a notified body take where a manufacturer wishes to add a new Model / Type to their existing Module C2 scope following either additional Module B certificate(s) being issued, or extension(s) of (an) existing Module B certificate(s)?		
Solutions: The notified body may include the new Model / Type / Module B certificate(s) within the existing Module C2 scope provided they are of the same type in so far as testing is concerned (i.e. changes do not affect Annex III (h) and (i)(e.g. new model reference for identical product, or cosmetic change that is permitted within existing Technical Documentation). This should be done without an additional sampling (i.e. between regularly scheduled product checks), and on the basis of a statement / application confirming the above, subject to successful review and decision. If the following change, this may have implications for the internal production control system, and consequently how the NB evaluates the adequate statistical sampling and compliance of the products made: a) The documented quality system; and b) The general manufacturing process (e.g. equipment); and c) The production locations. Note: Changes may be positive, and lead to closer compliance, and homogeneity. Where the above provision is not met (paragraph 1), or there are negative implications about changes made (items a to c), and the manufacturer does not wish to wait until the next regularly scheduled product checks, the notified body should conduct sampling of the new Model / Type of the Module B certificate(s) so that Product Checks may be conducted. The extent of those Product Checks may be full or reduced, based on the nature of the provisions not met.		