

CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425

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Origin : Ad-Hoc C2/D			 □ Vertical Group ⊠ Horizontal Committee □ EU PPE Expert Group 	20/03/2025
Question related to	PPE Regulation	EN/prE	N:	Other:
Article:	Annex: VII / VIII Module C2 / D	Clause:		
Key words: Notified body change				
Question: How may a manufactu	rer change module C2 or D notified	body?		
Solution:				
The process of change	e is subject to the following:			
- Manufacturers must t	erminate the contract with the curre	nt Notified Body.		
	o supply the new Notified Body with proval. This may require an on-site s			••

- The existing Notified Body may require a final C2 / D surveillance.

- The existing Notified Body has the authority to tell the manufacturer when they must stop applying their number to the products. This to be in accordance with the validity of the approval decision, i.e. once the approval is withdrawn the NB number to no longer be applied.

- New product cannot be marked with the new Notified Body number until a contract is agreed with the new Notified Body.

- New product being placed on the market after approval by the new Notified Body must have the new Notified Body number.

- Existing product displaying the original Notified Body number (in stock, or already in the supply chain prior to the change in Notified Body and being made available to the market) can continue to be supplied indefinitely with the original Notified Body number, presuming no objections by the original Notified Body, no proven non-compliance, and no evidence of the PPE being unsafe.