



CO-ORDINATION OF NOTIFIED BODIES
PPE Regulation 2016/425
RECOMMENDATION FOR USE

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Article:	Annex: VII / VIII Module C2 / D	Clause:	
Key words: Notified body change			
Question: How may a manufacturer change module C2 or D notified body?			
Solution: The process of change is subject to the following: - Manufacturers must terminate the contract with the current Notified Body. - Manufacturers have to supply the new Notified Body with all necessary information for the Notified Body to process their application and issue a new C2 / D approval. This may require an on-site sampling visit / audit before a new approval is issued. - 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 This to be in accordance with the validity of the approval decision, i.e. once the approval is withdrawn the NB number to no longer be applied.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.			