



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

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- Vertical Group  
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Question related to  PPE Regulation

EN/prEN:

Other:

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, but generally this will not apply.
- 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 This to be in accordance with the validity of the approval decision, i.e. once the approval is withdrawn the NB number to no longer be applied
- Product cannot be marked with the new Notified Body number until approval is given by the new Notified Body.
- Product being placed on the market after approval by the new Notified Body must have the new Notified Body number.
- Product 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.