



CO-ORDINATION OF NOTIFIED BODIES  
PPE Regulation 2016/425

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Version 1

RECOMMENDATION FOR USE

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Question related to	<input checked="" type="checkbox"/> PPE Regulation	<input type="checkbox"/> EN/prEN:	<input type="checkbox"/> Other:
Article:	Annex:	Clause:	
Key words: own brand certificates			
Question: How should applications for own brand certificates be dealt with?			
Solution: See attached			

## Own brand manufacturers type-examination certificates, Module B.

Any person / company / organisation placing a product on to the market in their own name is the manufacturer of that product within the terms of the PPE Regulation. It then follows that the manufacturer must make an application in their own name and be issued with certificates that support the CE marking of the PPE.

It is common practice for original manufacturers to offer their product to one or more companies who wish to sell the product as their own. There will be no identifiable link back to the original manufacturer in the market place.

The product offered for sale by the own brand manufacturer will be identical to the original product except for marking and probably user instructions. All other elements of the technical documentation can be applied to the own brand product.

The own brand manufacturer will be required to raise and sign a declaration of conformity before placing CE marked product on the market. This will include a statement covering modules C2 or D for category III PPE.

The own brand certificate will only remain valid while the cross-referenced original certificate remains valid.

As the own brand manufacturer is legally responsible for ensuring that the product(s) meet the requirements of the PPE Regulation, it is necessary for the minimum acceptable level of control and responsibilities to be established with the PPE notified bodies.

Proposed conditions to be fulfilled before the granting of certification for an own brand product: -

1. The original manufacturer to hold a valid type-examination certificate and if category III, to provide evidence of current supervision in line with module C2 or D.
2. Written agreement to be submitted, signed by both parties (original manufacturer and own brand manufacturer), covering the following:
  - Confirmation that the PPE subject to the current application is physically identical to product xxx, which is covered by type-examination certificate yyy.
  - Any difference between the original submission and this application to be listed.
  - Confirmation from the original manufacturer that only product fully compliant with type-examination certificate xxx will be supplied to own brand manufacturer yyy as the specified model.
  - Confirmation that the original manufacturer will advise the own brand manufacturer of any changes affecting the validity of either the type-examination certificate and for category III PPE, the supervision in line with module C2 or D.
  - Any proposed changes to the product will be sent to both the notified body and the own brand manufacturer before proceeding with the change.
  - Confirmation that the original technical documentation will be made available to the own brand manufacturer's notified body to support their application for certification and, for category III PPE, module C2 or D supervision.
  - Confirmation that both the original manufacturer and own brand manufacturer will inform each other of any incidents involving the products covered by the agreement
3. A copy of the EU type-examination certificate from the original manufacturer plus any documents that differ from the original technical documentation, e.g. marking and user information and access to the original technical documentation.  
 The notified body should review the user information and labelling of the own brand manufacturer in order to confirm it meets the requirements of the PPE Regulation.  
 A copy of the technical documentation amendments is then to be maintained by the own brand manufacturer and will be subject to review by the notified body during any ongoing surveillance activities.
4. For category III PPE, the notified body carrying out module C2 or D supervision will decide during the review of the own brand manufacturer's submission, activities etc., whether or not the premises of the own brand manufacturer need to be visited in the module C2 or D supervision.
5. The type-examination certificate issued to the own brand manufacturer will identify them as the manufacturer and will only reference the model identity as used by the own brand manufacturer. It is proposed that the original certificate does not need to be referenced on the certificate, but the NB holds this information, should it be required.