	CO-ORDINATION OF NOTIFIED BODIES **PPE Regulation 2016/425** **RECOMMENDATION FOR USE**	PPE-R/00.047 Version 04

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Question related to ☒ PPE Regulation ☐ EN/prEN: ☐ Other:

Article: Article 12 Annex: V, VII, VIII Clause:

Key words:

Own Brand Manufacturer (OBM) / Certificates / Approval Decisions

Question:

How may the PPE Regulation requirements be met when an OBM applies for module B, C2 or D?

Solution:

They may be met by applying Page 2 – Module B, Page 3 – Module C2, Page 4 - Module D, and Page 5 - RfU 00.047 agreement covering OEM / OBM modules C2 and D, as necessary.

Notes:

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, Article 12.

It then follows that the manufacturer must make an application in their own name and be issued with a Module B type-examination certificate (and if applicable Module C2 or D approval decision) that support the CE marking of the PPE.

It is common practice for original equipment manufacturers (OEMs) 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 OEM in the marketplace.

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

The OBM will be required to raise and sign a declaration of conformity before placing CE marked product on the market.

If category III, this will include a statement covering modules C2 or D for category III PPE.

The OBM certificate / approval will only remain valid while the cross-referenced OEM certificate / approval remains valid.

As the OBM 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.

The Proposed solutions of this RfU offer a way to manage OBM applications, of types Module B, C2, and D. These solutions only apply where the Notified Body has also issued the OEM certification, i.e. OBM must apply to the same Notified Body.

Module B.

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

1. The OEM 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 (OEM and OBM), covering the following:

a. Confirmation that the PPE subject to the current application is physically identical to product xxx, which is covered by type examination certificate yyy.

b. Any difference between the original submission and this application to be listed.

c. Confirmation from the OEM that only product fully compliant with type-examination certificate xxx will be supplied to OBM yyy as the specified model.

d. Confirmation that the OEM will advise the OBM 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.

e. Any proposed changes to the product will be sent to both the notified body and the OBM before proceeding with the change.

f. Confirmation that the original technical documentation will be made available to the OBMs notified body to support their application for certification and, for category III PPE, module C2 or D supervision, while maintaining the confidential nature of the original technical documentation toward the OBM
Market Surveillance Authorities have a right to request Annex III Technical Documentation of any 'manufacturer', therefore there must be a mechanism by which the OBM can obtain or provide access to their technical documents and those of the OEM.

g. Confirmation that both the OEM and OBM 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 OEM 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 OBM 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 OBM and will be subject to review by the notified body during any ongoing surveillance activities.

4. The type-examination certificate issued to the OBM will identify them as the manufacturer and will only reference the model identity as used by the OBM. It is proposed that the original certificate does not need to be referenced on the certificate, but the Notified Body holds this information, should it be required.

Module C2

Proposed conditions to be fulfilled before the granting of Module C2 certification / approval for an own brand product: -

1. The OEM to hold a valid Module B certificate and Module C2 approval.

2. The OBM to hold a valid Module B certificate.

3. A copy of the original Module B OBM agreement.

4. Application form to include agreement that access to the OBM site will be allowed if determined as necessary by the Notified Body.

5. Additional conditions.

a. The Notified Body can decide on a case by case basis whether or not OBM product is to be included within the C2 samples.

It is possible to combine the samples. But a sample must be taken from each OBM to check the label/user information. Physical tests do not necessarily have to be performed on all samples.

b. The OBM C2 approval will only remain valid while the OEM C2 approval remains valid.

If OBM and OEM samples are combined in product checks, all results must confirm compliance. If an OEM or OBM sample fails, the surveillance certificates / approval decisions cannot be issued until retesting confirms compliance.

c. The assessment of OBM product can be limited to marking and user info.

d. Samples to verify compliance with C2 to be selected within the supply chain (i.e. anywhere from OEM premises to distributor sites). Sampling at OEM premises may make selection of multiple OEM/OBM products easier.

e. Future changes to the technical documentation to be supplied to the notified body.

6. A copy of the EU type-examination certificate from the OEM and the OBM to be supplied plus any documents that differ from the original technical documentation, e.g. marking and user information, and access to the original technical documentation.

7. A C2 certificate / approval is issued to each OBM and will identify them as the manufacturer and will only reference the model identity as used by the OBM. It is proposed that the original certificate / approval does not need to be referenced on the certificate, but the Notified Body holds this information, should it be required. The C2 certificate / approval shall also be linked to the actual production site(s). This may be identified on the certificate / approval by code numbers or similar or held within the Notified Body records.

Module D

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

1. The OEM to hold a valid Module B certificate and Module D approval.

2. The OBM to hold a valid Module B certificate.

3. A copy of the original Module B OBM agreement.

4. Application form to include agreement that access to the OBM site will be allowed if determined as necessary by the Notified Body.

5. Additional conditions.

a. The Notified Body can decide on a case by case basis the level of QS documentation to be supplied by the OBM.

b. The Notified Body can decide on a case by case basis whether or not the OBM site is to be included within the module D audit process.

c. General view within Notified Bodies is that where an OBM does not alter the product or packaging, e.g. receives / stores / supplies the product, a remote audit of the OBM at the OEM site is possible.

Where the OBM does alter the product and / or packaging, e.g. receives product in bulk and repacks into smaller commercially available units, the OBM site would be audited at least initially. Audit to be limited to only those aspects affected by the OBM.

d. The OBM D approval will only remain valid while the OEM D approval remains valid.

e. Future changes to the technical documentation to be supplied to the notified body.

6. A copy of the EU type-examination certificate from the OEM and the OBM to be supplied plus any documents that differ from the original technical documentation, e.g. marking and user information, and access to the original technical documentation.

7. A D certificate / approval is issued to each OBM and will identify them as the manufacturer and will only reference the model identity as used by the OBM. It is proposed that the original certificate / approval does not need to be referenced on the certificate, but the Notified Body holds this information, should it be required. The D certificate / approval shall also be linked to the actual production site(s). This may be identified on the certificate / approval by code numbers or similar or held within the Notified Body records.

RfU 00.047 agreement covering OEM / OBM modules C2 and D

Written agreement to be submitted, signed by both parties (original equipment manufacturer and own brand manufacturer) covering the following:

1) Confirmation that the scope of the current OBM application falls within the scope of the OEM C2 / D** approval / certificate reference yyy;(**Delete as applicable)

2) The OBM will provide their technical documentation;

3) Confirmation that the OEM will advise the OBM of any changes affecting the validity of the supervision in line with module C2 / D**; (**Delete as applicable)

4) Confirmation that both the OEM and OBM will inform each other of any incidents involving the products covered by the agreement;

5) Confirmation that both the OEM and OBM will inform each other of any complaints or issues identified by market surveillance authorities involving the products covered by the agreement;

6) OBM confirms that they recognise the OEMs C2 / D internal production control, as part of their own;

7) Confirmation that upon receipt of an Approval / Certificate, the OBM will retain appropriate records associated with the products for 10 years after each PPE has been placed on the market.