	CO-ORDINATION OF NOTIFIED BODIES **PPE-Directive 89/686/EEC + amendments** **RECOMMENDATION FOR USE**	CNB/P/00.130 Revision 04 Language: E

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Origin : Article 11 Ad Hoc Group		☐ Article 11 Ad hoc group ..... ☒ Horizontal Committee 12.05.2011 ☒ Standing Committee .....

Question related to: Directive 89/686/EEC	EN/prEN:	Other:
Annex: Article:	Clause:	

Key words:

Own-brand certificates

Question:

How should applications for own brand certificates be dealt with?

Solution:

See attached

Sent for information to: ☐ members of the VG ☐ other(s) VG ☒ HC (2) ☐ TC (3) ☐ SC (4) ☒ other (5)

(5) EU Commission

(1) Essential safety requirement
(2) HC = horizontal committee
(3) N° of CEN/TC (Secretary & Chairman)
(4) EEC Standing Committee 89/392
(5) To be specified

Own Brand manufacturers type-examination certificates, Article 10.

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 Directive. 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 file can be applied to the own brand product.

The own brand manufacturer will be required to raise and sign an EC declaration before placing CE marked product on the market. This will include a statement covering article 11 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 directive, it is necessary for the minimum acceptable level of control and responsibilities to be established with the PPE notified bodies.

The own brand certificate can only be issued by the notified body that issued the original certificate or holds the original file.

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 11.A or 11.B supervision.

2. Written agreement to be submitted, signed by both parties (original manufacturer& 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 article 11 supervision.
   - 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 file can be used to support the application for certification and for category III PPE, article 11 documents.
   - 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 EC type-examination certificate from the original manufacturer plus submission of any documents that differ from the original technical file, e.g. marking and user information, and access to the original technical file.

   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 Directive.

   A copy of the technical file 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 article 11 notified body 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 article 11 supervision.

5. The type-examination certificate issued to the own brand manufacture 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.