NB-MED (European Co-ordination Notified Bodies)	**Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**	**Recommendation** **NB-MED/2.5.5/Rec 5**

Title:	**Conformity Assessment of Own Brand Labelling**
Chapter:	2.5.5 Conformity assessment for particular product groups

Text:	"'manufacturer´ means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party"
Key words:	Own Brand Labelling, Conformity Assessment, Manufacturer

1. Purpose of this Recommendation

The purpose of this recommendation is to provide a clear explanation of the "own brand labelling" situation, to give guidance on a consistent description for all parties to use, including manufacturers and Notified Bodies. It introduces a common approach for the conformity assessment of own brand labelling that can be used by all Notified Bodies.

2. Introduction

All three members of the medical device Directives family : the Active Implantable medical device Directive (AIMD), the Medical Devices Directive (MDD) and the In Vitro Diagnostic medical devices Directive (IVDD), define a company or person as the legal manufacturer of a device when he takes responsibility for placing it on the market under his own name. His legal responsibility for compliance with the relevant Directive and affixing the CE Marking is irrespective of whether he actually performs the design and manufacturing activities himself or the activities are carried out on his behalf by a third party, such as a sub-contractor or supplier.

The specific situation which is usually described as "own brand labelling" (OBL), is where the legal manufacturer purchases finished medical devices from the original entity who has already placed that product on the market as a CE Marked device (usually called the "original equipment manufacturer" or OEM). The purchasing organization will be selling the same device for the same intended use but the device is re-labelled with their own name and branding, thus they become the legal manufacturer. They have now taken legal responsibility for the device and they must follow the appropriate conformity assessment procedure depending on the class of device in order to place it on the market themselves, applying their own CE Marking. Very common examples of this situation occur with self-test IVD devices such as

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home use pregnancy tests or with medical devices such as contact lens or condoms.

In this situation, the "own brand labelling" manufacturer is basing the compliance of his device on the existing CE Marking compliance of the original manufacturer that he purchased the completed device from. The conformity assessment procedure he uses should take this existing approval into account. This recommendation is intended to provide guidance on what documentation should be held by an OBL manufacturer, which would be assessed by a Notified Body if required by the conformity procedure.

3. Definitions and Explanations

Definition of Legal Manufacturer – Article 1 of MDD and IVDD, AIMD
'Manufacturer´ means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name.

Description of "Own Brand Labelling" manufacturer
"Own brand labelling" manufacturer means the person or company re-labelling a device with existing CE Marking from a third party with his own name (brand) without making any other changes to that device, thereby taking responsibility for it as the legal manufacturer under the above definition. The term "private label manufacturer" is also used to describe this situation.

Explanation of what is NOT covered by the "own brand labelling" situation
There are other situations where a legal manufacturer may not actually carry out any design or manufacturing activities themselves, but have them performed by third parties on their behalf and they are placing it on the market for the first time (sometimes called a "virtual" manufacturer). There may also be a situation where the legal manufacturer is purchasing finished devices to label with their own name but which have not already been CE Marked by the original manufacturer.

In these cases, the situation would not be described as "own brand labelling" as identified in this recommendation. This is simply the legal manufacturer taking responsibility for the device and he will have to follow the appropriate conformity assessment procedure defined in the applicable Directive for that class of device – there is no existing CE Marking approval to take into account so he must fully demonstrate compliance with the Directive requirements.

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An example of the difference would be :
Where Notified Body intervention is required, an OBL manufacturer would simply have to demonstrate to the Notified Body that he has access to the technical documentation of the original manufacturer holding the existing CE Marking approval. It has already been assessed by a Notified Body so does not have to be assessed in full again.

For a legal manufacturer re-labelling a device with no existing CE Marking, the Notified Body would need to assess the full technical documentation for the device to verify compliance with the Directive.

4. Conformity Assessment Procedure

The conformity assessment procedure will be defined by the Directive applying to the device (AIMD, MDD or IVDD) and according to the classification of the device. In all cases the requirements of the Directive apply to the legal manufacturer, regardless of the fact that he is “own brand labelling”.

The conformity route will dictate whether the intervention of a Notified Body is required. Where a Notified Body is involved and is seeking to verify the compliance to the Directive then he must take into account the existing conformity approval for CE Marking and amend the assessment accordingly.

This guidance therefore gives general principles that should apply to all appropriate conformity routes.

5. Documentation required by Notified Body

The conformity assessment relating to the device itself will consist of verifying that the existing CE Marking conformity approval held by the OEM manufacturer (the “third party” providing the device to the “own brand labelling” manufacturer) is valid and current, and that the device in question is the same device. The assessment therefore needs to cover sufficient documentation to demonstrate this, including (but not limited to) :

- Declaration of Conformity from “own brand labelling” manufacturer
- Index for technical documentation / design dossier (version/date), listing supporting documents such as reference to OEM manufacturer’s Technical File
- Copies of the current CE Marking conformity approval and quality systems approval (if applicable) from the original CE Marking manufacturer of the device, including last assessment reports from their Notified Body if possible, and a copy of their Declaration of Conformity

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- Contract agreement between "own brand labelling" manufacturer and the original CE Marking manufacturer. This should include :
  - clear identification of the devices covered, product specifications
  - OEM manufacturer will maintain his CE Marking and quality system approvals, and notify of any certificate withdrawal or change
  - OEM manufacturer to provide notification of significant changes / vigilance reports / product recalls and corrective actions taken
  - access to technical documentation for OBL manufacturer or at least direct access for regulatory parties such as the Notified Body or Competent Authorities
  - OEM manufacturer to maintain the records and other documentation relating to the batches being "own brand labelled" for an agreed period of time
- Labelling, including packaging information and instructions for use
- Copy of the OEM manufacturer's device Instructions for Use/packaging, to allow confirmation that the same claims are being made for the device

The conformity assessment will also need to cover the mandatory quality system requirements to ensure that the "own brand labelling" manufacture can meet the Directive obligations as the legal manufacturer, including documents for :

- Vigilance and Post Market Surveillance procedures
- procedures for labelling of the device and display of the CE marking.
- procedure to prepare and review a Declaration of Conformity
- process to identify what is a significant change and what should be notified to the Notified Body,
- procedures for registration with Competent Authorities according to Article 10 (98/79/EC) or Article 14 (93/42/EEC)
- process for selection and control of the OEM manufacturer, demonstrating responsibility for design, manufacture and labeling of the product

Any additional activities carried out by the OBL manufacturer within the context of "own brand labelling" would also be subject to assessment by the Notified Body and appropriate relevant procedures/ documented processes should be provided, for example actual re-labelling of devices.

Where the classification requires conformity assessment by a full quality assurance route, the OBL manufacturer will need to demonstrate 'design control' procedures, even though in effect they have sub-contracted the design activities

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to the original manufacturer.

6. Surveillance

The requirements for surveillance under the appropriate Directive apply to "own brand labelling" manufacturers. Depending upon the specific conformity assessment procedure, the "own brand labelling" manufacturer will be required to supply information at regular intervals to demonstrate continuing compliance:

- confirmation that the OBL/OEM agreement is still in place and unchanged
- confirmation that the OEM manufacturer still has a valid conformity certificate / quality system certificate for the products covered and that product range/scope has not changed
- no significant changes to the devices
- confirmation that vigilance reports have been correctly dealt with

For List A IVD's, the "own brand labelling" manufacturer will still need to comply with IVDD Annex IV para 6 and provide the relevant reports and tests for verification of manufactured product for each batch to be placed on the market, as agreed with his Notified Body.

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	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	**Rationale and history sheet to NB-MED/2.5.5/Rec 5**
Title:	**Conformity Assessment of Own Brand Labelling**	

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Draft proposed by Ms S Williams (LRQA). Discussed, comments to be sent.

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Draft updated by Ms S Williams (LRQA), taking into account comments from BSI, SGS, INFARMED, DNV, TUV PS, LRQA and others.
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