



LNE/G-MED North America, Inc.
Your Global Quality Partner



CE Marking of Own Brand Label Devices: Manufacturer Benefits and Requirements

September 2011

Companies often seek to rebrand existing medical devices and sell them under their own name. This process is called Own Brand Labeling and offers faster market entry for companies wishing to build and complete their product portfolio compared to developing a new product.

The regulatory status of an Own Brand Labeler (OBL) continues to cause confusion, as discussed in the May issue of the *Journal of Medical Device Regulation*. The European regulation, similar to regulations in countries such as the U.S. and Canada, considers the OBL the legal manufacturer even when the OBL has nothing to do with the actual manufacturing or design process. As a result, the regulation holds the OBL to conform to legal and technical requirements over which it arguably has little to no control. This proves to be counterintuitive and problematic with many companies who may not have bargained for the extra responsibility. Moreover, specific approaches remain in the individual European member-states and other international regions.

Figure 1: Common Terms for OBL Participants
In Own Brand Labeling, one company sells and/or distributes another manufacturer's device under a different brand. Common terms for each of the manufacturers involved include:

- **Company Rebranding Product:** Own Brand Labeler (OBL), Private Brand Labeler (PBL), Private Label Manufacturer (PLM)
- **Original Manufacturer:** Original Equipment Manufacturer (OEM), Original Equipment Supplier (OES); Actual Manufacturer; Contract Manufacturer

This month's newsletter explores the OBL process, including how LNE/G-MED works with its clients to assist in the OBL procedure to understand the requirements to secure CE marking.

Specific areas covered include:

- Responsibilities of the OBL and OEM
- Role of the Notified Body
- Situations where a lighter OBL approach apply

The OBL is the "manufacturer" of the product when a product is labeled with the OBL name and contact information. As a result, the OBL assumes the corresponding "manufacturer" responsibilities according to the applicable European Directive¹.

¹ INTERPRETATION OF THE MEDICAL DEVICE DIRECTIVES IN RELATION TO MEDICAL DEVICE OWN BRAND LABELLERS - http://ec.europa.eu/consumers/sectors/medical-devices/files/guide-stds-directives/interpretative_fiche_obl_en.pdf

The Directives explicitly state that the manufacturer is responsible for the design, manufacture, packaging and labeling of the device, regardless if these operations are carried out by either the company or on its behalf by a third party. The Directive expects the OBL to address all relevant requirements related to product design and the quality management system. Therefore, qualifying the OBL as a “virtual manufacturer” or “distributor” is misleading, giving the false idea that the OBL has less regulatory responsibility than a manufacturer actually making the products. This is not, in fact, the case.

Responsibilities of the OBL and the OEM

The OBL is different from the Original Equipment Manufacturer (OEM), or the manufacturer that actually, physically (as opposed to virtually) manufactures the device. As a result, the OBL and OEM have slightly different responsibilities with regards to the

Directives and the device. The OBL must satisfy the requirements for the device’s class and assessment route for the CE marking (annex(es) of the Directive) to apply the CE Marking on the product. Typically, a technical document must exist and a Quality Assurance System implemented if it is required.

Obviously this covers the device’s distribution, marketing and post-market activities, such as post-market surveillance and complaints. Less obvious is that the OBL is directly responsible for following the regulations regarding design, manufacture and other aspects normally handled by the Original Equipment Manufacturer (OEM). The OEM, however, has the most direct expertise and experience with a device’s intrinsic characteristics. While the OBL is allowed to delegate these activities, it still has the direct responsibility relating to these aspects of the finished device.

Because of the linked responsibilities, transparency is necessary between both parties to ensure access to all relevant information for the compliance demonstration. A contract between the OBL and the OEM is essential to clarify the role of both parties and to specify modalities for communication and access to critical information. For example, since the OEM designed the product, it may consider some information proprietary and want to restrict access to the most sensitive parts. This could create problems for the OBL if it does not have complete information about the product during the compliance demonstration.

The contracts should address at least the following:

- Activities covered by the OEM’s quality assurance system to support the OBL’s compliance;
- Communication about the status change of the certification of the OEM products;

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Figure 2: Scenarios

In the below examples, A is the Original Equipment Manufacturer (OEM) and B is the legal manufacturer, typically designated as “OBL”. All these situations can be considered acceptable in the framework of the European regulations. Essentially, the scenarios vary in the extent of the involvement of the OBL in the design and manufacturing activities. Their liability with regards to the CE marking of the considered device is identical.

Scenario Where B is Typically Qualified as OBL	Eligibility for LNE/G-MED OBL Procedure
A: Manufactures and sells CE marked device B: Sells/distributes same device, rebranded. <u>A re-labels</u> the device prior to selling to B.	Yes
A: Manufactures and sells CE marked device B: Sells/distributes same device, rebranded. <u>B re-labels</u> the device after purchasing it from A.	No
A: Manufactures and sells device <u>not</u> CE marked B: Sells/distributes same device, rebranded, once receiving CE mark. (Who re-labels is irrelevant.)	No
A: Manufactures and sells CE marked device B: Has A make a variant, customized to their need, not covered by A’s Technical Documentation.	No

- Ways to access the technical documentation, the product specifications, production records and the duration of time the documents and records are retained (at both the OEM and the OBL);
- Communication about changes to the product specifications;
- Decision making processes and authorities for accepting a non-conforming product by concession;
- OBL surveillance methods for activities implemented by the OEM;
- Communication about any medical device complaint received by either the OEM or the OBL alleging deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device, including communication on complaints for similar devices, as relevant;
- Decision making processes and authorities relative to medical device reporting (vigilance) and recalls;
- Considerations for specific requirements from the Directives, as applicable, such as the communication about new variants of transmissible spongiform encephalopathies (Directive 2003/32/EC) or change of pathogen (Directive 98/79/EC – List A device).

The Directives require that the OBL's quality management system and choice of assessment approach ensure a proper survey of its covered activities, such as:

- Control of labeling activity;
- Control of the receiving, warehousing, shipping of the product;
- Control of the distribution network;
- Control of translation of product information, including the instructions for use, as applicable;
- Implementing risk management approach to justify the relevance and sufficiency of these controls.

Figure two mentions different scenarios that apply in specific instances. The contract may need to be adjusted based on the scenario.

When the OBL, as the legal manufacturer, fulfills all the regulatory obligations, it has the authority to issue the corresponding CE declaration of conformity.

Role of the Notified Body

A notified body, such as LNE/G-MED, is responsible for assessing the manufacturer's quality system and the technical documentation compliance with the applicable European Medical Device Directive(s).. As indicated above, the European regulations do not provide for specific OBL assessment. The general assessment rules therefore also apply to the OBL as in any case where the manufacturer delegates critical activities to a third party.

While assessing an OBL's device and quality system, LNE/G-MED takes into account the OBL's particular situation in the design and manufacture of its device and the OEM's CE certification. LNE/G-MED adjusts the audit at the OBL's (legal manufacturer) facility to take into account the activities that need to be assessed. The need to audit the OEM facility may be waived provided the OEM is appropriately certified.

Situations Where the LNE/G-MED OBL Specific Procedure Applies

In response to the different manufacturers' regulatory responsibilities, LNE/G-MED developed an optimized procedure of assessing an OBL when the devices are strictly identical to the devices for which the OEM holds CE certificates, with the exception of their market identity.

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LNE/G-MED follows the optimized procedure on these conditions:

- The device is CE marked by the OEM (the supplier is not an OBL himself) for its own behalf;
- It is supplied by the OEM to the OBL as a finished labeled product and the OBL does not modify the device or relabel it;
- The CE marking by the OBL has the same assessment route as the OEM's;

LNE/G-MED offers an OBL a streamlined audit and an adapted audit schedule (typically every 18 months depending on the result of the initial audit). This allows LNE/G-MED auditors to review the contractual terms and reciprocal commitments of the manufacturers involved, along with other activities implemented at the OBL location. The OBL's Notified Body does not need to be the same Body that assessed the OEM quality system or the technical documentation.

As for the implementation of this procedure, the CE marked devices of the OBL and the OEM are identical, any post-market issues with one device would similarly affect the other, making the above contractual relationships and express communication routes essential to ensure the proper vigilance of both devices. This would be a key-part of the audit.

When the so called LNE/G-MED OBL procedure can not be implemented, a regular assessment is carried out.

How LNE/G-MED Can Work With You

The different roles of the OBL and the OEM can create issues with regulatory certification. This is especially true when the parties don't consider how their relationship and interactions affect each others' regulatory certification. As a result, these issues can slow down, or even block, an OBL's market access for its devices. It is not LNE/G-MED's intention to push manufacturers to work within the frame of this LNE/G-MED OBL specific procedure. All the scenarios of the chart above can be considered and some may make more business sense. The assessment by the notified body should not be the only driving force for making such strategic decision. But LNE-GMED can help manufacturers consider all aspects of the OBL and OEM relationship. LNE/G-MED has already considered the crucial aspects of the relationship between the OBL and the OEM, and so can bring its experience to analyze all sides of each scenario, which is beneficial for both the OBL and OEM.

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