Own brand labelling of medical devices –
Clarification on current expectations for CE certification

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Abstract
This article examines the historical and current regulatory expectations for CE certification of devices under the “own brand labelling” (OBL) route, and identifies the key legal obligations that such manufacturers should be aware of prior to undertaking such a route to market.

Introduction
“Own brand labelling” (OBL) (also referred to as “private labelling”) is the terminology used to describe the situation in which a person or organisation places devices on the market under their own name or trademark, where those devices have already been subject to appropriate conformity assessment under the directive for the same intended use by another organisation, ie, the original device already bears the CE marking.

The original holder of the CE certificate is known as either the “Original Equipment Manufacturer” (OEM) or “Original Equipment Supplier” (OES). The OBL-issued CE certificate piggybacks on the existing CE marking certificate held by the OEM; however, the OEM is not disclosed on the OBL manufacturer’s certificate. The CE marking placed on the devices will be associated with the identification number of the notified body (NB) chosen by the own brand labeller. Own brand labelling does not apply to:
- Organisations which change (other than the representation of the “manufacturer” placing the devices on the market) the device, including its intended use, compared to the device as originally conformity assessed and CE marked
- Devices sourced from suppliers and to be placed on the market in the name of a “new” manufacturer, those devices not having previously been subjected to appropriate conformity assessment under the Directive
- Organisations which fulfil the definition of a “manufacturer” for placing devices on the market, but which do not themselves perform all the required activities and have, therefore, “sub-contracted” any of those activities to other parties. Examples of such activities are design and/or production
- Distributors which sell on other manufacturer’s devices but do not themselves take the responsibility of “manufacturers” by relabelling the devices.

Historical approach for conformity assessment for OBL manufacturers
Across the three device directives in Europe: Active Implantable Medical Device Directive 90/385/EEC,1 Medical Device Directive (MDD) 93/42/EEC,2 and In Vitro Diagnostic Directive 98/79/EC,3 the definition of what constitutes a manufacturer is identical:

“Natural or legal person with responsibility for the design, manufacture, packaging and labeling [sic] 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 specific situation which is usually described as OBL is where the legal manufacturer purchases finished medical devices from the original entity which has already placed that product on the market as a CE marked device (the OEM). The devices the OBL brands as its own cannot be modified from the OEM’s version and typically only are purchased, stored and marketed under the OBL’s own name. Thus, the labelling (label and instructions for use) cannot be altered drastically, except for modifications to the device name or trade name, or for modifications to improve the label. As the purchasing organisation (OBL) will be selling the same device for the same intended use under its own name and branding, it takes on all the legal responsibility for the device associated with being the manufacturer, which includes the requirement to follow the appropriate conformity assessment procedure for the risk classification class of the device, and the generation of a “Declaration of Conformity” and application of the CE mark.

A key and critical point is that in this situation, the OBL manufacturer is basing the compliance of its device on the existing CE marking compliance of the original manufacturer from which it purchased the completed device. The conformity assessment procedure used by the OEM and the existing approval was taken into account during the conformity assessment process for the OBL manufacturer.

The Medicines and Healthcare products Regulatory Agency (MHRA) Bulletin No 191 provided guidance on the expectations for OBL manufacturers to meet regulatory requirements, which meant that the OBL manufacturer needed to ensure the following:
- The appropriate conformity assessment procedure is correctly followed by the OBL manufacturer and any sub-contractor
- If appropriate, an application is lodged with an NB. (In the MHRA’s view, any existing NB approvals to the sub-contractor remain valid and must be recognised by any subsequent NB. The subsequent NB may thus only need to review the contract between the “own brander” and the sub-contractor, and the documents confirming existing NB approval)
- Any NB which may be involved and the competent authority (CA) have access to the appropriate documentation necessary for them to fulfil their respective responsibilities
- It makes a declaration of conformity for the products concerned, and retains them for future reference by CA
- The CE marking of conformity is properly applied
- Post-marketing obligations such as vigilance are satisfied.
To meet the above requirements, the standard approach taken by OBL manufacturers was as follows:

- Establishment of a technical or quality agreement between the OBL and OEM entities, to delineate the respective responsibilities for each party, such as the OEM’s obligation for document retention.
- Implementation of standard operating procedures for post-marketing surveillance (PMS) and a medical device vigilance system by the OBL manufacturer.
- A review of the OEM’s essential requirements checklist, declaration of conformity and CE marking certificates, by the OBL if NB involvement is necessary for CE marking.
- For Class I self-certify (self-declaration) medical devices, the OBL would self-certify the medical device and apply the CE marking, provided the documents such as the quality agreement was in place between parties.

Where NB involvement was mandated because of the classification of the device, the OBL manufacturer submitted for review to its subsequent NB: OBL and OEM labelling (label and instructions for use); OBL and OEM declaration of conformity; technical and quality agreement between the OBL and OEM; the OEM’s CE marking certificates, and the OBL’s standard operating procedures for post-marketing surveillance and a medical device vigilance system.

However, due to consistent harmonised approach across EU member states, differences in approaches between NBs with respect to the conformity assessment process for OBL manufacturers developed. Many of the UK NBs issued CE certification to the OBL manufacturer on the basis of the validity of the OEM certification and the satisfactory assessment of OBL labelling and the contractual agreements between parties as satisfying the legal requirements. Meanwhile, other NBs, including LRQA, held the position that the agreements between parties as satisfying the legal requirements. Meanwhile, other NBs, including LRQA, held the position that the agreements between parties as satisfying the legal requirements.

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- Commission Regulation 920/2013 on the designation and the supervision of notified bodies.
- Commission Recommendation 2013/473/EU on the audits and assessments performed by notified bodies in the field of medical devices.

The above requirements further defined the expectation for the conduct of audits of the OBL manufacturer’s QMS as well as specifying the need for the OBL manufacturer to hold technical documentation for the devices. These additional requirements caused concern in the industry from both OBL manufacturers, in terms of quality management system implementation, as well as OEMs which felt it unreasonable to be expected to share the technical knowledge and manufacturing know-how for their device(s), leaving them vulnerable to the use of their proprietary knowledge by alternative and cheaper subcontract manufacturers.

Impact of EU Commission actions to improve device safety

Following the discovery of a 16-year fraud in PIP breast implants using low quality “industrial grade” silicon oil, a review was conducted by the EU Commission. The conclusions of this review determined that changes were needed to improve early detection and prevent this type of incident. At the same time, many other high-profile vigilance cases occurred within the medical devices sector, such as metal-on-metal hips and pelvic floor meshes. As a result of this review, the European Commission and EU countries took joint action to tighten controls, provide a better guarantee for the safety of medical devices, and restore confidence, resulting in the publication of the “Joint Action Plan for Immediate Actions” under existing medical device legislation (the so-called “PIP action plan”).

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The release of the Commission Recommendation 2013/473/EU on 24 September 2013 had significant impact for OBL manufacturers, specifically, Annex II of 2013/473/EU included a section of “general advice in case of outsourcing of the production via subcontractors or suppliers” which states:

“Critical subcontractors or crucial suppliers may be suppliers of suppliers or even suppliers further down the supply chain. Notified bodies should refrain from signing arrangements with manufacturers unless they receive access to all critical subcontractors and crucial suppliers and thus to all sites where the devices or its crucial components are produced, regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier. Notified bodies should note that manufacturers:

a) Have to fulfil their obligations themselves regardless of any partial or total outsourcing of the production via subcontractors or suppliers
b) Do not fulfil their obligation to have at their disposal the full technical documentation and/or of a quality system by referring to the technical documentation of a subcontractor or supplier and/or to their quality system
c) Should integrate the quality system of critical subcontractors and of crucial suppliers with their quality system
d) Need to control the quality of services provided and of components supplied and the quality of production thereof regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier.”

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Since the publication of the recommendation, the MHRA has been extremely proactive on this subject, to ensure a pragmatic solution to the concerns raised by industry can be reached. At this time, the MHRA also provided additional guidance to UK NBs and to industry on its position with respect to expectations for OBL manufacturers to meet regulatory requirements following the implementation of Commission Recommendation 2013/473/EU. This draft guidance included:

- Additional detail on requirements for contractual obligations between the OBL and OEM, such as:
  - The requirement for a direct link between OEM/OBL’s products
  - The requirement for the inclusion of a clause allowing access to the OEM’s full technical documentation by NBs and regulatory authorities
  - The need to allow access to the OEM to conduct unannounced audits
  - Clear arrangements for PMS/vigilance activities
  - Keeping the OBL informed of changes
- The draft guidance further outlined that the contract cannot be with another OBL but must be directly with the OEM
- The draft guidance also detailed that if appropriate, the OBL manufacturers were expected to implement a “quality system” as a minimum to meet the relevant conformity assessment annex
- As a minimum, the OBL manufacturer should maintain an abridged or summary technical file for each product
- The OBL manufacturer’s NB is required to carry out its routine sampling of technical documentation for Class IIa/IIb devices, to provide the NB with sufficient confidence about the device’s safety and performance
- The possibility to obtain the OEM NB’s technical documentation reviews or the OEM’s full technical file
For product, type and design dossier examinations – NBs are required to review the technical documentation themselves in sufficient depth to confirm safety and performance. An initial meeting was held between the MHRA, UK notified bodies and industry on 10 October 2014 to further discuss the details of the draft guidance with the key stakeholders. At this meeting, the main wish expressed by all participants was the implementation of an approach that would allow for harmonisation across EU member states.

While the above position adopted by the UK in 2014 was generally aligned with the other EU member states and the Commission, the level of technical documentation held by the OBL manufacturer remained a point of concern and debate, and as a result the 2014 draft guidance has been updated, but not yet formally published.

Future requirements for OBL manufacturers
As indicated previously, much work has been done within the UK and across Europe to ensure a harmonised approach across all EU member states with respect to the conformity assessment for OBL manufacturers. As a result of the discussions, and given the expectation of the EU Commission, it is now proposed that OBL manufacturers shall be required hold the full technical documentation and make this available their NBs for review.

It is anticipated that the MHRA guidance document will be updated and that this will be published on the MHRA website by the end of March 2016. UK NBs were requested to contact their OBL clients by the end of March 2016 to advise them of the requirement to hold the full technical documentation, with a six-month transition period from 1 April 2016.

Conclusion
Following the implementation of the PIP action plan to provide a better guarantee for the safety of medical devices while also restoring public confidence in the system, there has been an increase and strengthening of regulatory requirements across the medical sector. From recent discussions it is concluded that the conformity assessment requirements for OBL manufacturers are identical to that of “virtual” manufacturers, therefore making the term “own brand labeller” redundant.

Given the significant changes in the area of OBL in the last two years, manufacturers choosing this route to market for medical devices need to be fully aware of the amended expectations to ensure they can meet the current regulatory requirements. OBL manufacturers also need to be mindful of the possible need to revisit their current contractual arrangements with the OEM to ensure their needs can still be met.

References