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Private-Label Manufacturing – A How-To Guide

Introduction

Synonymous with the term "own-brand labelling", the practise of private-labelling is very widespread across the medical devices and in-vitro diagnostics industries, and both familiar to and accepted by, the regulatory authorities involved[1].

Private-labelling is the purchasing of finished product that is subsequently placed on the market bearing the brand identity of the purchasing company.
Thus manufacturers who wish to maximise their market penetration can create partnerships with established sales companies who wish to affix their brand name to a wider product range, to the benefit of both parties.

Whilst it is generally well understood that all medical devices within the now-expanded EEA must bear the CE mark, the subsequent division of the regulatory responsibilities that a private-label CE mark brings with it is often rather less straightforward.

In common parlance, the producer of the finished product is known as the Original Equipment Manufacturer (OEM) and the sales company is known as the Private-Label Manufacturer (PLM), or Own Brand Labeller (OBL).

Articles 1.2f of both the MDD and IVDD give the same definition of the "manufacturer", and the UK Competent Authority (MHRA) reinforces this description in its useful guidance document on this subject[2]. For simplicity, the rest of this article will make reference only to the MDD, however the requirements of the IVDD similarly apply.

Responsibilities

As the company whose name is appearing on the box – regardless of how much involvement in the actual preparation of the product it has had – the PLM must take full regulatory responsibility for that product. Thus the PLM must meet all relevant elements of the MDD or IVDD, including maintaining its own Declaration of Conformity, as well as applying to a Notified Body for any supporting EC certifications required.

In a private-label situation, it is therefore important that the agreements between the OEM and the PLM cover not just the commercial terms, but also the regulatory responsibilities of the two organisations.

Many companies, who already operate as either OEMs or PLMs, have created their own templates for such regulatory agreements. Pre-designed templates are also available for purchase and are highly recommended for companies that are new to this area. In any

event it is generally worthwhile to separate the commercial and regulatory arrangements into two different documents.

Key Elements of a Private-Label Agreement

Whilst private-label arrangements are technically possible under Annexes III IV, and VI, these are relatively rare. This article will therefore focus on what needs to be in place under Annexes II, V, and VII.

For devices in Class I (non-sterile, non-measuring), there will be no Notified Body involvement, however the requirements of Annex VII will still apply. Those requirements include the need for the PLM to register the product with the relevant Competent Authority, and the need to appoint an Authorised Representative if the PLM is based outside Europe. The PLM must create its own Declaration of Conformity, however this can be based on a template supplied by the OEM.

The PLM must include within the agreement the ability to make all the technical documentation immediately available to the Competent Authority. This documentation must remain available for at least five years after the last product has been manufactured.

That means the OEM and PLM need to reach agreement on a wide variety of issues relating to how the technical documentation will be maintained. There should be clear identification of how both the initial design and subsequent changes to the product ranges can be proposed and agreed, and how those changes will be controlled and documented. This is obviously of particular importance in relation to Instructions For Use and packaging labelling.

The agreement should also include details of who will hold and maintain the technical information and make it available to the Competent Authority. These arrangements are of particular concern where confidentiality of design or manufacturing is an issue between the OEM and PLM. It is on this issue that the details of such technical agreements can often vary the most, depending on the extent to which the OEM wishes to share his proprietary technical information with the PLM.

Additionally safeguards need to be in place in case the commercial agreement comes to an end (including as a result of the OEM ceasing to trade), as the PLM may remain responsible for providing technical documentation for several years afterwards.

The agreement must ensure that appropriate post-market surveillance, vigilance, and advisory notification and recall systems are in place. Traceability, timescales, and the authorisations for decision-making, reporting, and action, must all be adequately defined. The PLM must maintain appropriate documented procedures to enable its vigilance responsibilities to be met[3].

Where the device is Class IIa or higher, or a Class I device that is sterile or has a measuring function, the PLM will require an EC certificate issued by a Notified Body in advance of placing the product on the market.

The PLM will need to make an application to their Notified Body under the relevant Annex. Whilst procedures and requirements between Notified Bodies will vary slightly, the PLM will need to prepare basic documentation for audit.

This documentation will include a copy of the OEM's EC certificate(s), a copy of the signed technical/regulatory agreement, comprehensive drafts of the IFUs and packaging information, and copies of other internal procedures as demanded by the Notified Body (including vigilance reporting arrangements, and the requirement to advise the Notified Body in advance of any significant changes). It will also be important to clearly identify to the Notified Body the brand names of the products involved.

Although the PLM's Notified Body will recognise the validity of the OEM's EC certificate, it will have some documentation review activity to perform, and may reserve the right to audit the PLM directly. It can be advantageous for the PLM to employ the same Notified Body as that used by the OEM, but this is not mandatory. Where the Notified Bodies are different, it will of course be the number of the PLM's Notified Body that is used alongside the CE mark.

Special situations

There are a few special situations that are also worth briefly describing.

The MHRA has long held the position that if more than one company name / brand appears on the packaging, the most prominent name / brand is the one that the MHRA will hold to be responsible for the CE mark. As a result, even explanatory descriptors such as "manufactured for…manufactured by…" should be used with considerable caution.

Recent MHRA guidance[4] suggests a possible option in situations where a device carries the names and addresses of both the PLM and the OEM. The guidance proposes that the PLM could exclusively licence the right to use its name/trademark back to the OEM to the exclusion of all others, for that device.

Situations can arise where the private-labeller is also involved in aspects of the design or production processes. Whilst these cases are not uncommon, additional care must be taken to ensure the PLM arrangement is fully legitimate.

Further private-labelling of an existing private-label arrangement is technically allowed, but often the contractual arrangement between an OEM and its original Private-Labeller will specifically preclude private-labelling by a third party. Even if not, the arrangements for vigilance reporting, recall actions, and access to technical documentation may make commercial secrecy difficult anyway.

In addition, the various parties, including any involved Notified Body, must ensure that communications between the parties will be effective and are properly enshrined in appropriate contracts. In particular, great care must be taken to ensure that vigilance reports and corrective activity like recalls will not fall outside the designated timescales.

Companies that wish to private-label Class III devices, or whose OEM has achieved conformity under Annexes III, IV or VI, should liase closely with their Notified Body as these routes often require additional oversight activity by the Notified Body.

[1] *Private-Label Manufacturing* – Medical Device Technology, December 1997, Rob Lally, BSI Medical Devices Certification

[2] *Own Brand Labelling and Rented Products* – MHRA Bulletin 19, published August 1996, revised April 2003. www.medical-devices.gov.uk

[3]MEDDEV 2.12 – Guidance on vigilance systems
http://europa.eu.int/comm/enterprise/medical_devices/meddev/index.htm

[4] MHRA *Key Topic* – Own Brand Labelling, January 2004

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Product Certification- Medical Devices

Position Paper on Own-Brand / Private Label Manufacture

The Medical Devices industry is characterized by extensive own-brand or private labelling of devices where a company purchases finished devices from another supplier except that the packaging bears their own name, logo etc. To all intent and purpose the product as placed onto the market purports to be that of the "own-brander". The original equipment supplier may make the same product available to several different "own-branders" at any particular time.

The Medical Devices Directive 93/42/EEC (the MDD) covers these arrangements in that the "manufacturer" is defined as the entity responsible for placing devices on the market under their own name irrespective of whether the actual design and manufacturing processes are undertaken on their behalf by another body, the original equipment supplier. Therefore the "own-brander" is legally the "manufacturer" within the context of the MDD.

The original equipment supplier in many cases also places the product onto the market in their name and probably has already determined their compliance with the MDD including appointment of a Notified Body to monitor requisite conformity assessment procedures. Conversely the "own-brander" may have little technical expertise with the product or processes or even with the complexities of regulatory requirements.

A key point is that the legally defined "manufacturer" becomes responsible for compliance with the MDD and must put in place certain arrangements to fulfill their obligations. These arrangements can be effected in conjunction with the original equipment supplier and build from their compliance.

The MDD requires the "manufacturer" to have a **quality system** that satisfies the requirements of, generally, Annex II or V - however they do not actually manufacture the product. The requirement is clear that the "manufacturer's" quality system must **ensure** that appropriate controls are exercised over devices and that post-market surveillance/vigilance systems are effective. Regarding the actual design and production systems, BSI is prepared to accept approvals of the quality system issued by other MDD Notified Bodies as evidence towards the "manufacturer's" compliance. Where the supplier is unable to furnish such evidence of approval they will require to be assessed by BSI as a normal fully finished goods supplier.

The MDD requires the "manufacturer" to make a legal **declaration** that devices meet the specified requirements and to **maintain appropriate documentation**. This "technical documentation" should be fully maintained at the original equipment supplier but will probably contain a level of detail that will be unavailable to the own-brander. Access to the documentation both during the supply period and for a suitable period after cessation of the supply must be a contractual condition between the two parties as the information needs to be kept at the disposition of the European Commission for at least 5 years after placing onto the market.

The attached checklist will assist with establishing compliance.

Following demonstration that these mechanisms have been adequately addressed BSI will issue the own-brand manufacturer with approval for:

"The own-brand manufacture of [xyz devices] produced on their behalf by
[original equipment supplier details] and subject to full production approval by
[OES Notified Body details] in accordance with the provisions of Annex
[II or V] of the Medical Devices Directive 93/42/EEC"

Further references

UK Medical devices Agency guidance bulletin number 19 "Own-brand labelling and rented products"

R K Lally article in Medical Device Technology, Dec 1997.

OWN-BRAND / PRIVATE LABEL CHECKLIST

Product details .....

Original Equipment Supplier .....
Address .....
OES product name .....
Details of OES Notified Body approval .....

"Manufacturer" specification/contract reference .....

Who is responsible for compliance of artwork
on label and instructions etc .....

Where is the following technical documentation retained ?
Description of product and variants .....
Design drawings .....
Methods of manufacture .....
Risk analysis .....
Evidence of compliance with
all Essential Requirements .....
If sterile, details of protocol and validation .....
test reports, clinical data .....
Label and instructions for use .....

Is access to documentation covered in contract .....
Documentation retention period .....

Will documentation and facility access
be made available to manufacturers agent (NB) .....

Outline formal arrangement to exchange market / production
experience after placing on the market .....
.....
.....

Describe "manufacturer" system for vigilance reporting .....
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Describe the system for advising each party and the
Notified Body of any changes to the product or process .....
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