

Client Communication: 5th February 2016

Dear BSI Client,

Own Brand Labelling (OBL) – Clarification.

Following the publication of the EU recommendation 2013/473/EU, we wrote to you regarding the impact on Own Brand Labelling (OBL) Manufacturers. We have since introduced onsite Quality System audits, Unannounced audits, and Technical Documentation assessments for OBL Manufacturers. We would now like to provide further clarity around the implications for Own Brand Labelling based on further guidance given to Notified Bodies.

Background information.

The changes follow the CE Marking Medical Devices – European Commission Recommendation of 24th September 2013 (2013/473/EU) on the audits and assessments performed by Notified Bodies in the field of medical devices. The following link to the EU Commission website will take you to the document: [European Commission Recommendation of 24th September 2013 \(2013/473/EU\)](#)

BSI under its designation by the UK Competent Authority is implementing the above recommendation under the Guidance of the MHRA.

What are the main implications of this Guidance to an OBL Manufacturer?

OBL manufacturers depend on the EC certifications already held by their Original Equipment Manufacturers (OEMs) and hence required reduced or limited conformity assessments by the Notified Body. The previous reduced assessment requirements placed on OBL manufactures no longer exist.

As a legal manufacturer, all the requirements of the medical devices directives must be fulfilled by the OBL manufacturer and Notified Bodies are now required to carry out full conformity assessments as per the applicable directives.

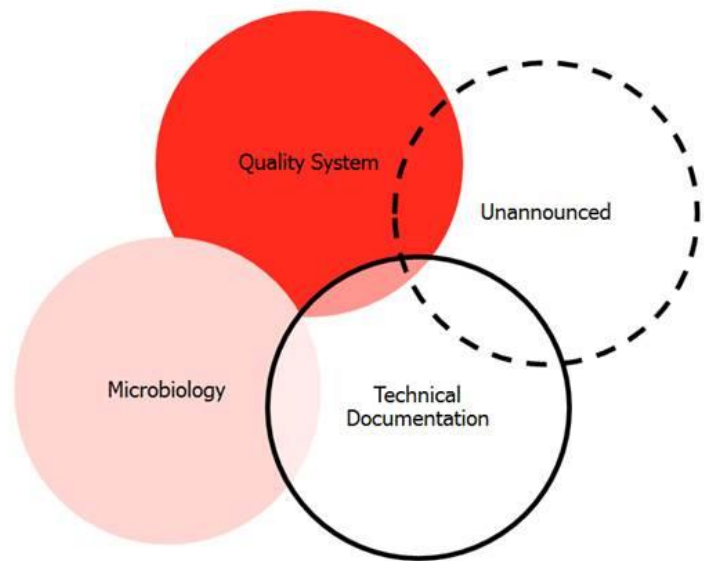
The Commission Recommendation emphasizes the following points:

The legal manufacturer must be able to show compliance to the full requirements of the medical directives:

- Understanding, systems and controls to fulfil all legal and regulatory responsibilities.
- An ability to receive unannounced audits at the physical location(s) of the legal manufacturer and critical subcontractors and crucial suppliers. Contracts are required to ensure access for the Notified Body or Competent Authorities.

- For the devices you have legal responsibility of, you must hold the full technical documentation.

In practice this means, OBL Manufacturers must plan their assessment strategy **like all other legal manufacturers**, fulfilling the following aspects of conformity assessment:



What happens to my current OBL certificates?

Your current certificates remain valid, but you should begin to complete a gap analysis against the new requirements immediately, talk with your Notified Body to review your individual situation.

How can BSI help?

We strongly suggest you review the impact on your organization, in particular in relation to your ability to provide BSI with the technical documentation of your devices for review on request.

For impartial information on technical documentation and for guidance on meeting the requirements of the medical device directives please refer to the Guidance documents on the EU website:

http://ec.europa.eu/growth/sectors/medical-devices/guidance/index_en.htm

If you have further questions regarding this update please contact your BSI Scheme Manager in the first instance.

Thank you for your continuing support.

Yours faithfully

Suzanne Halliday

BSI UK Head of Notified Body