

**Client Communication: 20<sup>th</sup> July 2016**

Dear BSI Customer

Further to our 5<sup>th</sup> February 2016 communication concerning changes to CE Marking expectations regarding Own Brand Labelling (OBL), we are now providing an update.

[See the 5<sup>th</sup> February 2016 communication.](#)

As explained in our previous communication the current European expectation is that all OBL's are legal manufacturers and for CE marking to continue the following conditions must be fully satisfied (this is additional to previous OBL requirements):

- Conformity assessments must be completed appropriate to the classification of the devices under the certification.
- OBL manufacturers must have full technical documentation to support CE Marking.
- OBL manufacturers must hold full CE Marking certificates (not limited OBL certificates) to support their CE Marking declarations of conformity.
- OBL manufacturers are subject to unannounced visits.

It is the responsibility of every OBL manufacturer to ensure they are in full compliance with the above requirements. To fully meet these requirements OBL manufacturers may need to submit to the Notified Body additional information including full technical documentation (if this has not been previously submitted). For all BSI OBL manufacturer customers please ensure that as soon as possible (if not already complete or in progress) the following requirements are understood and addressed:

- OBL/Private Label certificates will no longer be acceptable after 1 December 2016
- For all class III, AIMD and IVD Annex II List A/B devices that require a design examination certificate please ensure that a full design dossier is lodged with BSI to support CE Marking
- For all IIa, IIb medical devices please confirm with your BSI Scheme Manager the sampling plan for your technical documentation (BSI must have evidence that the plan for sampling technical documentation has been implemented)

**Failure to agree a technical file auditing plan and /or submit full technical documentation by 1st December 2016 will result in withdrawal of your OBL CE Marking certificates.**

If you require more information please contact your BSI Scheme Manager.