



## BREXIT UPDATE

### MEDICAL DEVICES

SGS continues to monitor the developing political landscape with respect to Brexit and notes the rejection by the UK Parliament of the proposed deal between the EU and UK. We believe that a so-called “hard Brexit” remains unlikely but we recognize that, in the current levels of uncertainty, everybody has to prepare for the unknown.

Neither SGS, nor any other UK Notified Body, can make any guarantees with respect to the post-Brexit position. The most likely scenario remains business as usual until at least December 2020. However, if the UK does crash out of the EU without a deal, there is no clarity at all about what the situation will be. At the one extreme, it is possible that UK-issued certificates may immediately be invalid; this continues to be the position of the EU Commission. There is, however, a strong belief that a more pragmatic position will have to be adopted within the EU 27 in the face of potential supply and availability issues. This would see UK certificates recognized for an as-yet-to-be determined transitional period, allowing an orderly transfer to Notified Bodies remaining in the EU.

It is also possible that there may not be a fully co-ordinated response at an EU level, with different positions being adopted by different Competent Authorities. Customers with concerns about a particular country are encouraged to contact the relevant Competent Authority to identify their current thinking on their local approach to post-Brexit arrangements.

SGS is the only UK Notified Body with well-established, functioning Medical Devices Notified Bodies within the EU 27. These are based in Belgium and Finland and both long pre-date the Brexit issue. For most clients, these will provide an effective solution should transfer become necessary. However, there will need to be a formal process for transfer, which will be published shortly.

We are continuing with our plan to extend the scope of our Notified Body in SGS Belgium to cover those elements of the UK Scope not currently addressed. The timing of this, however, is not entirely in our hands and will not now be completed before the formal Brexit deadline. However, assuming a pragmatic position is adopted within the EU we are confident that these arrangements will be operational within any transition period and again allow for an orderly transfer. In the worst case, there are established procedures within the EU framework for “orphaned products”, which would presumably come into effect in the immediate aftermath of Brexit in the event that the EU does not implement alternative arrangements.

Customer contracts with the SGS United Kingdom Notified Body will continue and we will remain approved by our regulator, the MHRA. Our certificates will continue to be recognized in the UK market by the MHRA, with whom we are working closely to ensure that, at least at a local level, there is minimal disruption to the regulatory process.

Should a hard Brexit materialize, it is unlikely that we will see reciprocal recognition of EU bodies in the UK beyond December 2020, especially if the certificates of UK bodies are no longer accepted in the



EU. SGS intends to continue work in the UK market, and to continue to progress our MDR designation; we will also be amongst the first bodies to seek approval under any new certification arrangements established by the MHRA.

We recognize that until the political situation is resolved, it is unfortunately impossible to provide definitive guidance. SGS will continue, however to ensure that you are kept up to date with developments as they arise and that we adapt our contingencies accordingly.

Useful links:            latest updated MHRA updated [technical notice](#)  
                                 EU Commission's [notice to stakeholders](#)

Keep up-to-date with news on SGS Services and Brexit at [www.sgs.co.uk/brexit](http://www.sgs.co.uk/brexit)