BSI's role as an EU Medical Devices Notified Body

BSI's role as an EU Notified Body will not change following the recent UK decision to leave the European Union.

The triggering of Article 50 on 29 March 2017 marked the start of a period during which the UK government will be negotiating the arrangements for its withdrawal from the EU and its future terms of trade with Europe and the rest of the world.

During this time BSI will be working closely with the Medicines and Healthcare Products Regulatory Agency (MHRA) and Department of Health to ensure continuity of our full scope designation as a Notified Body for Medical Devices.

BSI is fully confident in continuing as the leading global provider of EU Medical Device Notified Body services by utilizing established well recognized existing mechanisms for non-EU member states to fully participate as EU Notified Bodies. Examples are the designated organizations in Norway (under EEA recognition), Switzerland and Australia (through Mutual Recognition Agreements) all of whom are recognized as Notified Bodies for the purposes of the relevant EU legislation.

Going forward we aim to provide a seamless transition within a new designation recognition mechanism as part of any UK – EU framework/Relationship once this is finally established. Our sole aim is for the transition to be effectively invisible to you our clients, leaving you unaffected from a market access perspective.

Our current primary focus is on track for BSI to be in the first wave of Notified Bodies designated under the recently passed (April 5th) 2017 Medical Device regulation and 2017 IVD Regulation, and we are continuing to invest heavily to ensure we meet this objective. IGZ and RVA witnessed and surveillance audits are being scheduled, this will enable us to be one of the first EU Notified Bodies to offer full conformity assessment under the new regulations.

In parallel we are well on our journey in partnering to transition all our clients to the ISO 13485:2016 standard. Furthermore, BSI is the leading global provider within the Medical Device Single Audit Programme Pilot and again we are investing heavily with a view to leading the final programme to be announced in early 2017.

We will continue to keep you updated on a regular basis as the political situation develops and discussions progress. For now, it's business as usual and most importantly, we would like to assure you that BSI will continue to provide EU market access as we have done since the inception of the three EU Medical Device Directives.

All of these activities, combined with our specialist expertise, are designed to give our clients unrivalled services in the regulated Medical Device market access arena.