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Recent European Commission article regarding future recognition of UK Notified Bodies: January 2018

Client Communication

You may be aware of a recent article published by the European Commission regarding the future recognition of UK Notified Bodies in the EU. This article outlines the worst-case where no withdrawal agreement is achieved. We expect this won't happen and fully anticipate that a mutual recognition agreement will be achieved.

We have been working closely with UK government departments – such as the Department for Business, Energy & Industrial Strategy; Department for Exiting the EU; and the Medicines & Healthcare products Regulatory Authority – to ensure they understand the implications not only for UK Notified Bodies but more importantly our clients and patients who use these products.

BSI is Europe's leading Notified Body for high risk medical devices; EU commission data indicates that two thirds of medical device products entering the EU use UK Notified Bodies. As with most large UK companies, we have a contingency plan in place to ensure that our clients can continue to use BSI as their European Notified Body.

For the BSI Medical Device Notified Body, this includes establishing a presence at our offices in the Netherlands to ensure we maintain our status as an EU Notified Body. BSI has formally applied for:

- Designation as a Medical Device Notified Body in the Netherlands under the EU Directives: (90/385/EEC) Active implantable medical devices, (93/42/EEC) Medical devices and (98/79/EC) IVD devices within the oversight of the Dutch Health and Youth Care Inspectorate (IGJ). IGJ have completed our initial Audit and we are working through the process of designation.
- ISO 13485 accreditation under the Dutch Accreditation Council (RVA) and we have received our initial assessments. The RVA accredits management system certification bodies based on the ISO/IEC 17021 standard.

We will continue to keep you updated as the negotiations progress. For now, 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.

If you have any questions or concerns, please contact your Scheme Manager.

Yours sincerely,

Gary Slack

SVP Global Medical Devices

For all general enquiries call +44 845 086 900 or visit the BSI Group website

Our mailing address is:
BSI Medical Devices
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP

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