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Dear Chief Executive Officer, Managing Director, Senior Site Executive,

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.

As a valued client of our Notified Body, I write to you personally to make you aware of the changes to the roles and responsibilities of Notified Bodies under the provisions of the above EU Commission Recommendation.

The following link to the EU Commission website will take you to the document:

Commission Recommendation 2013/473/EU

These changes not only impact BSI as a Notified Body, but also your organization as a legal manufacturer of medical devices placed on the market in the European Union.

Unannounced Audits.

The last sentence of point (5) of the Recommendation 2013/473/EU states:

"*To verify the continuous compliance with legal obligations, Notified Bodies should perform unannounced audits in addition to product assessments and quality system assessments*".

All Notified Bodies must comply with this requirement to undertake unannounced audits; Annex III of the Commission Recommendation contains the full details.

How will this affect my Company?

BSI must implement a routine program of unannounced visits to all our CE-certified manufacturers and, if appropriate, their critical sub-contractors and crucial suppliers. Annex III of the recommendation details the frequency and required expectation for these unannounced audits.

The legal provision for unannounced visits exists within the three current Medical Device Directives (MDD 93/42/EEC, AIMD 90/385/EEC and IVDD 98/79/EC), and Unannounced audits are subject to our Standard Terms & Conditions; this provision is stated in Para 4.3. However, we are reviewing the relevant detailed procedures to ensure we comply fully with the European Commission Recommendation and we strongly propose that you do the same.

BSI recognises the need for financial budgeting and planning so, as we will need to charge for such additional audits, please allow for the additional costs within your financial planning processes. We are currently finalising our charging structure, as indicated in our recent 2014 Pricing Communication Letter.

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What additional obligations will these new requirements place upon my company?

All companies must permit and allow unimpeded access for Notified Body staff to conduct unannounced audits; this is a legal requirement in order to maintain your EC Certification or CE Mark approval. Without these it is illegal to place products on the EU market.

BSI routine surveillance audits will also include aspects relating to unannounced audits. For instance we will confirm a company's awareness of the requirements and review its processes for handling these audits. Please ensure all of your staff are aware of and prepared for the arrival of the Notified Body audit team at your premises or the premises of any of your major sub-contractors, regardless of location and time of the day.

When will BSI provide further information on these changes?

As we finalise our processes and procedures, we will communicate further updates to you. In addition we will be communicating in detail with the appointed contact within your company in order to ensure your organisation is fully briefed and understand the requirements and the role the Notified Body will take on under the provisions of this EU Commission Recommendation.

I thank you on behalf of BSI, for your support in meeting our shared obligations under this EU Commission Recommendation. If you would like further briefing on the subject, please do not hesitate to contact me or your medical devices Scheme Manager.

Yours faithfully

Gary Slack

Global Director, Medical Devices

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