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Malaysia appoints standard assessment firm

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Singapore: BSI, a global standard assessment company, has been registered by the Malaysian Medical Device Bureau as one of the three Conformity Assessment Bodies (CAB). In this role, BSI will be responsible for independently assessing medical device manufacturers, importers and distributors to ensure that they comply with Medical Devices Act 2012.

Depending on the classification of medical device, the assessment process will comprise several steps, including medical devices approval review that is necessary prior to registering the device with the Medical Devices Bureau, assessing the organization's medical device Quality Management System, (normally compliance to ISO 13485) and assessing to the Goods Distribution Practice for Medical Device (GDPMD) in accordance to the regulatory compliance set by the medical device Bureau for post-market surveillance.

The role of the Conformity Assessment Body has been created by the Medical Device Authority, part of the Malaysian Ministry of Health, in response to the new Malaysian Medical Devices Act 2012. All medical device manufacturers in Malaysia will have less than two years to comply with the regulation to register their medical devices. Importers and distributors will have under one year to obtain an establishment license to import and distribute medical devices locally in Malaysia.

In order to register their medical device, be certified to a Quality Management System and/or attain certification to the GDPMD, medical device organizations will need to appoint a Conformity Assessment Body.

Mr Gary Slack, global director, Medical Devices, BSI, said that, "The new regulatory requirements will ensure the safety, effectiveness and quality of medical devices being imported, developed and manufactured in Malaysia. By implementing and enshrining regulation at a local level, Malaysia can make more informed choices on the medical devices used within their healthcare system. BSI Group is delighted to be one of the first Conformity Assessment Bodies registered. This appointment is a great honour, further enabling BSI's expertise to help protect even more patients globally by ensuring their safety is always the paramount consideration."

An additional benefit of implementing a globally harmonized approach to regulating medical devices in Malaysia is that it will help facilitate the export of locally manufactured products worldwide.

Mr Yap Liep Lin, MD, Singapore and <alaysia, BSI, explained, "This regulation will help facilitate international trade by reducing the regulatory barriers required for different regions and provide improved access to new technologies. As one of the world's leading medical device assessment bodies, manufacturers will benefit from the expertise and knowledge BSI can bring to the getting products to market not only in Malaysia but around the world."