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Ortho-specialist appoints former J&J exec as CEO

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DDT
HONGKONG/LEIPZIG, Germany: Former Johnson & Johnson executive David N. Edwards will replace Dr Mervyn Fathianathan as CEO of BioMers, a Singapore-based company specializing in orthodontic appliances. Edwards, who has also worked for Bausch & Lomb and Nestlé, will take over the responsibilities for the company’s global business, starting immediately. Dr Fathianathan will remain Chief Technical Officer and oversee future development and research activities, the company said.

Founded in 2005, BioMers is a National Pore-based company specializing in orthodontic appliances. BioMers currently distributes its products in Singapore and the US only. The company is partially owned by Nanostart, a German-based venture fund with representation in Singapore.

New standard launched by ISO

GENEVA, Switzerland: Around 1.5 million different medical devices are available worldwide. Every year, thousands of new products are launched. The International Organization for Standardization (ISO) has introduced a new International Standard that aims to assess the safety and performance of such devices and to improve patient safety.

ISO is a global network that identifies international standards that are required by businesses, governments and society. The non-governmental organization develops these standards in partnership with the sectors that will put them to use, adopts them by transparent procedures based on national input and ensures that they are implemented worldwide.

According to ISO, the new standard ISO 14155:2011 will provide a technical basis for regulation and minimize technical barriers to trade. It was developed to encourage medical manufacturers to guarantee that their products do not compromise patient safety.

In 2007, the World Health Organization reported that more than one million accidents attributable to medical devices occur annually in the US. Furthermore, in some developing countries, half of the medical equipment was found to be unusable or only partly usable.

The new standard addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out on humans to assess the safety or performance of medical devices for regulatory and other purposes. This International Standard specifies general requirements intended to protect the rights, safety and well-being of humans and to ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results.

The requirements are also intended to define the responsibilities of the sponsor and principal investigator, as well as assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.