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Absorbable Hemostat "TDM-621" Product Registration Application Submitted in Singapore

The 3-D Matrix group is working towards commercialization of absorbable hemostat "TDM-621" globally. The company hereby announces that the subsidiary, 3-D Matrix Asia Pte. Ltd., has submitted the application for medical device product registration in Singapore on June 03, 2014.

The group has obtained CE marking for the absorbable hemostat "TDM-621" on January 14, 2014. This CE marking can be leveraged by using it as a reference regulatory agency approval in various countries in Asia-Pacific and Latin America. The product can be commercially marketed once approval is obtained in each country.

As the CE marking approval was utilized for application submitted in Singapore, clinical trials are not required. Hence, once the Singapore regulatory body, Health Sciences Authority, approves the product registration via the abridged evaluation route, commercialization activities can start.

The company is currently focused on product launch in Europe. In the meantime, 3-D Matrix Asia Pte. Ltd. is preparing for product registration in Indonesia, and plans to do the same in other markets in Asia-Pacific region, leveraging on the CE marking.

This announcement does not influence the earning forecast of the company at this moment.