



MEDICAL TECHNOLOGY

3-D Matrix Asia Pte. Ltd.

435 Orchard Road, 11/F Wisma Atria, Singapore 238877

TEL : +65- 6408-3858 / FAX : +65-6701-8001

(UEN:201225790E)

Keymax Technology (Hong Kong) Limited
Unit 2103, 21F, Kodak House II
39 Healthy Street East
North Point, Hong Kong
Tel: +852 3150 8913

Date: September 29, 2015

Letter of Notification Regarding Product Recall of PuraStat

Thank you very much for your continuous business and support.

Due to manufacturing process issue stated in details below, 3-D Matrix group has decided to recall the concerned lots.

Product name : PuraStat
Product reference no.: 621-015
Lots to be recalled : 15C05A50* and 15C12A50 (*15C05A50 only for Hong Kong)
Expiry date: February 2018
Product Owner: 3-D Matrix Europe SAS
Country of Manufacture: Japan

There is no harm to patient safety and there is no need to inform patient if the concerned lots have been used. This is a voluntary recall at the distributor level. Once the distributor have recalled all remaining syringes from the market and returned to manufacturer, there are no further actions required by distributor.

We would like to seek your kind cooperation on this matter and also sincerely apologize for the inconvenience caused.

<Details Leading to Recall>

PuraStat is a sterile product manufactured in accordance with ISO13408-1. As required by the ISO standard, in order to validate the aseptic manufacturing process, process simulation in the form of media fill test is conducted periodically.

The medial fill test had passed in January 2015, however failed in July to September 2015. Since we will not be in compliance with ISO13408-1 due to the failed medial fill tests, decision was made to recall all products manufactured between January and July 2015.

For every lot of PuraStat manufactured, sterility test is conducted to assure sterility of product. Hence, there is extremely low risk of health hazard. There are no safety issues or adverse events in relation to the affected lots reported till date.

We would appreciate your cooperation on the following actions;

- ✓ Recall all remaining syringes from the affected lot as soon as possible.
- ✓ Please quarantine all syringes from affected lot, including those recalled from hospitals and



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those stored at your premises or warehouse. It is fine to store at room temperature.

- ✓ We will require all recalled and quarantined syringes to be sent back to the address stated below. Kindly await for further instruction via email regarding shipment and logistics for the return of products.

Return Address:

Consignee: 3-D Matrix Asia Pte. Ltd.

Address (Warehouse):

SDV Logistics Singapore Pte Ltd

101 Alps Avenue, #03-01

Singapore 498793

Tel: +65 6408 3858 (3-D Matrix Asia), +65 6416 8333 (Warehouse)

Please do not hesitate to contact us anytime regarding this recall.

Contact Details:

Organization: 3-D Matrtix Asia Pte. Ltd.

Contact person: Yu Hosokai (Manager-Regulatory Affiars)

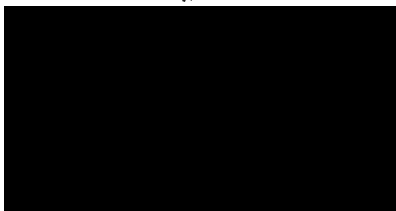
Tel: +65 6408 3858 (Office) / +65 9663 8873 (Mobile)

Fax: +65 6701 8001

Email: hosokai@3d-matirx.co.jp

Address: 435 Orchard Road, 11/F Wisma Atria, Singapore 238877

Yours sincerely,



Manager – Regulatory Affiars
3-D Matrix Asia Pte. Ltd.