

### Advisory Notice – Updated Product Labeling

## 1. New Product Catalog Numbers for My5-FU, MyDocetaxel, and MyPaclitaxel product lines

Catalog numbers for My5-FU, MyDocetaxel and MyPaclitaxel have been changed as shown in table 1. The catalog numbers have been updated in all product labeling and documentation, including package inserts and instrument application sheets. The information in this notice is for ordering purposes only. There are no changes to the product formulations, quality, or pricing.

 Table 1: New Product Catalog Numbers

Product	New Catalog Number	Replaces
My5-FU Reagent Kit	5FU-RGT	728-FNP
My5-FU Calibrator Kit	5FU-CAL	703-FNP
My5-FU Control Kit	5FU-CON	710-FNP
MyDocetaxel Reagent Kit	DTX-RGT	733-FNP
MyDocetaxel Calibrator Kit	DTX-CAL	736-FNP
MyDocetaxel Control Kit	DTX-CON	743-FNP
MyPaclitaxel Reagent Kit	PTX-RGT	747-FNP
MyPaclitaxel Calibrator Kit	PTX-CAL	750-FNP
MyPaclitaxel Control Kit	PTX-CON	757-FNP
MyPaclitaxel C111 Control Kit	PTX-CON-C111	757-FNP-C111

These labeling changes will go into effect with the next manufacturing lots. You may still receive kits with the former catalog numbers as we deplete the current product inventory.

# 2. The address of Saladax Biomedical's notified body, EMERGO, has changed. The change is reflected in all labeling.

The new address is:

EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands

#### **ACTIONS REQUIRED**

- Order products using the new catalog numbers listed in the product catalog available at <u>www.saladax.com</u> under Products section
- Obtain updated package inserts at <u>www.saladax.com</u>
- Destroy obsoleted documents
- Update EMERGO contact information

#### QUESTIONS

For questions or concerns pertaining to this Advisory Notice, please contact Saladax Technical Support by e-mail at techsupport@saladax.com or by telephone at +1-610-419-6731, Option 1.