

Urgent Field Safety Notice

Commercial name of the affected product: t-PSA Rapid Test and Free PSA Rapid Test

FSCA-identifier (e.g. date): 20190130

Type of action (e.g. chapter 4 definition of a FSCA): Destruction or return of t-PSA Rapid Test and Free PSA Rapid Test

Date: 30th Jan, 2019

Details of the affected products:

The affected products t-PSA Rapid Test (Part No.90.83.09.CT3508) and Free PSA Rapid Test (Part No.90.83.09.CT3509) are consumables used in CT3 Colloidal Gold-labeled Immunoassay Systems. For detailed shipment and tracking information please refer to attachment <List of Affected Products>

Description of the issue:

On 30th Jan, 2019, we received a complaint regarding incorrect information on a product label. After investigating the matter, we discovered that Dongguan Bosh Biotechnologies, Ltd., is wrongly labeled as the "Manufacturer" instead of as the "Distributor" of t-PSA Rapid Test and Free PSA Rapid Test which are consumables used in CT3 Colloidal Gold-labeled Immunoassay Systems.

Since the Original Manufacturer of these two products has got the CE approval for them, Dongguan Bosh Biotechnologies, Ltd. is the distributor, who hasn't made any change to the original products except adding Bosh information to the labelling, therefore, this issue has no impact on the safety and performance of these products, and will not cause risk to patients.

Advice on actions to be taken by the customers:

We suggest that distributors who received the affected products should:

- 1. After receiving this FSN, immediately cease all use of t-PSA Rapid Test and Free PSA Rapid Test as well as ceasing the distribution of these products to end-users. The FSN will be sent on 3rd Feb. 2019 via e-mail.*

- 2. For affected products within expiry date that have not been used, distributors should :*
 - (1) Destroy the affected products by cutting their packages according to their own protocol or local regulations. Meanwhile, evidence (e.g. photo, video or other documents) should be sent back to Dongguan Bosh Biotechnologies, Ltd.*

Or

(2) Return the affected products to EDAN Hong Kong Branch, below is the shipping information :

Consignee: EDAN Instruments, Inc.

Notify Party: Ship Air Express LTD.

Add: UNIT I, 6/F WING SHAN INDUSTRIAL BUILDING, 428 CHA KWO LING ROAD, YAU TONG KOWLOON HONG KONG

Attn: Celery Zhang

TEL: 00852-23828108

Either (1) or (2) operation should be finished before 15th March, 2019.

- 3. For affected products that have been used, since both of those two products have CE approval, this issue will not cause risk on safety and performance in clinical use, so further operation will not be conducted.*

Transmission of this Safety Notice: (if applicable)

This notice should be passed on to anyone who needs to be aware of this case within any organization where the potentially affected devices have been distributed (where appropriate).

Should you have any further questions, please reach out to either of the contacts found below:

Dongguan Bosh Biotechnologies, Ltd. Monday to Friday 09:00-17:00 (UTC +08:00)
Tel: +86-769-23324156
EDAN Instruments, Inc. Monday to Friday 09:00-17:00 (UTC +08:00)
Tel: +86-755-26898321

