



爱德检测科技有限公司  
AI DE DIAGNOSTIC CO., LTD.

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For the attention of all user for AIDE First Step Pregnancy Test

Date : 04/-5/2015

Subject : Urgent Safety Information

Error in the Arabic instruction for use for AIDE First Step  
Pregnancy Test


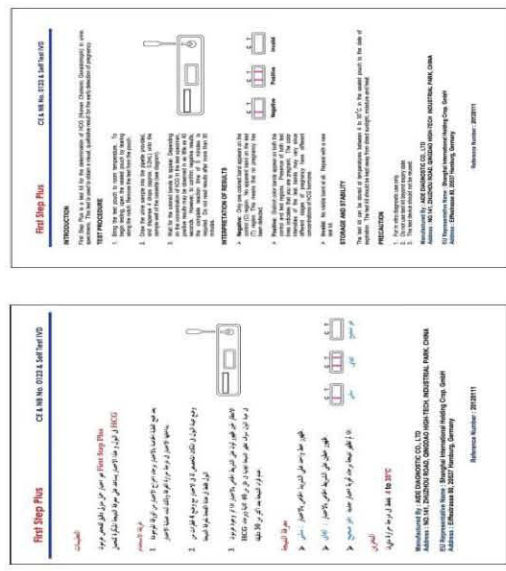
The information on the following pages is therefore pertinent for safety compliance :-



For the attention of :-

All people in charge of AIDE First Step Pregnancy Test eg. Pharmacies

**Identifying the affected medical products:**

 <p>SIZE:125x75x15mm</p>	 <p>Front      SIZE:11.5x6cm      Back</p>
<p>Item Name : First Step Test</p>	<p>Details : The Arabic Instruction For Use</p>



**Affected products :-**

<b>Item Name</b>	First Step Plus
<b>Manufacture Name</b>	AI DE DIAGNOSTIC Co., Ltd
<b>Device Type</b>	Pregnancy Test ( Single Use Device )
<b>Distributor</b>	Abdull Rahim Hazazy Trading Est.,
<b>Item No.,</b>	100-13
<b>Lot No.,</b>	LOT .:130417C6

**Reason of Field Safety corrective action :**

A client reported a case to SFDA , that he bought a pregnancy test (First step plus) from one of pharmacies with a mistake in the Instruction For Use in Arabic language .

**Action to be taken :**

**Measures to be taken by the parties in charge:**

**A- By our Authorized Representative :**

- Identify the product that have the old Arabic IFU.
- Replace the old Arabic IFU with a corrected Arabic IFU.

**B- By our operator :-**

- We contact with the factory AI DE DIAGNOSTIC CO., LTD and we confirm with them the right instruction for use and not make any problem in this item
- The date for the email that confirmed on it 19-4-2014



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**Forwarding the information provided in this letter**

- Please make sure that all users of the above product and any other relevant people within your organization are made aware of the above safety procedures. If you have transferred AIDE First Step Pregnancy Test to a third party, please forward a copy of this letter and of the enclosed materials to them or notify the contact person detailed below.
- Please circulate and keep this letter active until the measures described here have been fully implemented and completed.
- The Saudi Food & Drug Authority has been provided with a copy of the safety procedures as set out in this letter

**Contact Person :-**

Abdull Rahim Hazazy Trading & Contracting Est., Dr. Ahmed Sobhi  
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Email : [Hazazy\\_Medical@Hotmail.com](mailto:Hazazy_Medical@Hotmail.com)

We thank you in advance for your understanding and support.

Yours sincerely



Name : Mark Luis

Job Title : Manager of Foreign Trade Department