



**Guangzhou Wondfo Biotech Co., Ltd.**

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**Urgent Field Safety Notice**

**DEVICE RECALL**

Date: 1<sup>ST</sup> September 2018

Dear Healthpoint,

We regret to inform you that we have decided to recall the following product.

Product:	<b>Clear &amp; Simple Digital Pregnancy Test</b>
Catalogue number:	<b>DM-102</b>
Lot number	<b>DM10220170710E</b>
Device Mfr Date	<b>10<sup>th</sup> July 2017</b>
Expiry date.	<b>9<sup>th</sup> January 2020</b>

The Digital pregnancy test DM-102 (Lot No.: DM10220170710E) is producing a number of false positive results which is misleading to consumers. After investigation, the reason is that some rib height of the test strip brackets (Lot No.: 170708) that were used in the Digital pregnancy (Lot No.: DM10220170710E) are close to the lower limit of the acceptance which caused a large gap between the test strip bracket and the plastic enclosure of the Digital pregnancy. Therefore, it made a change in the light path of some products which eventually led to a larger signal value resulting in false positive results.

Please identify the abnormal products with the lot number DM10220170710E which can be found on the box and pouch. One case is to discontinue use and/or sale of affected product lots and place in quarantine immediately if you have products in your possession. The other case is to notify your customers/other facilities for a device recall if you have distributed any affected product to other facilities or customers. After the abnormal products are recalled to the address of Premier Gate, Staithgate Lane Bradford, West Yorkshire, BD6 1DW, you shall destroy the products under the supervision of Wondfo personnel locally and reserve the destruction



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evidences. After evaluating based on the risk we decide not to take measures for the products that had been sold to the end users. The basis of evaluation were that we described the information on the IFU “you should talk to your Doctor who can tell you what steps you should take next if the test result is Pregnant” and “if you want advice about your test call the manufacturer helpline”

If you need any further information or advice, please do not hesitate to contact me. Details are as follows.

Yours sincerely,

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