**PIHAK BERKUASA PERANTI PERUBATAN**
***Medical Device Authority***
**KEMENTERIAN KESIHATAN MALAYSIA**
***Ministry of Health Malaysia***
Aras 5 & 6, Prima 9, Prima Avenue II,
Blok 3547, Persiaran Apec,
63000 Cyberjaya, Selangor
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# MEDICAL DEVICE RECALL NOTICE

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| MDA REFERENCE NUMBER: | MDA/PMSV/R2018-080 |
| MEDICAL DEVICE NAME: | **Clear and Simple Digital Pregnancy Test**<br><br>Device Registration Number : N/A |
| AFFECTED BATCH NUMBERS: | • Catalogue Number - DM-102<br>• Lot Number - DM10220170710E<br>• Expiry Date - January 2020 |
| INTENDED USE: | Digital pregnancy test with conception indicator is intended for the disclosure of Human Chorionic Gonadotrophin (HCG) in urine, to aid in the detection of pregnancy. |
| RECALLING ESTABLISHMENT: | **Guangzhou Wondfo Biotech Co. Ltd. (Manufacturer)**<br><br>Licensing Number: N/A |
| REASON FOR RECALL/ALERT: | **This particular batch of device is producing false positive results.** |
| RECALL CLASS: | N/A |
| ACTION & RECOMMENDATION: | **Any individuals and/or premises who posses the above mentioned device are required to respond to this notice immediately and notify the Regulatory Authority on the action taken.** |
| REFERENCES (if available): |  |
| CONTACT: | For further information, please contact:<br><br>**Post Market Surveillance & Vigilance Unit**<br>**Medical Device Authority,**<br>**Ministry of Health Malaysia,**<br>**Aras 6, Prima 9, Prima Avenue II,**<br>**Block 3547, Persiaran APEC,**<br>**63000 Cyberjaya,**<br>**Selangor, MALAYSIA.**<br><br>**Tel : +603 - 8230 0300**<br>**Fax : +603 - 8230 0200**<br>**E-mail : mdb@mdb.gov.my**<br>www.mdb.gov.my |

**MEDICAL DEVICE AUTHORITY**
**MINISTRY OF HEALTH MALAYSIA**
**8th OCTOBER 2018**