

Safety Notice

Medical Devices

LOVEXOK One Step Pregnancy (HCG) Test Strips



Priority 2 – Warning

HPRA Safety Notice: SN2016(11)

Issue Date: 29th April 2016

SUPPLIER / MANUFACTURER	HPRA CASE REFERENCE
<p>The HPRA is aware that this product is available from, but may not be limited to, the following websites: www.amazon.com/shops/LOVEXOK www.dhgate.com/store/LOVEXOK</p> <p>The manufacturer is believed to be: Shenzhen Accurate Import & Export Co., Ltd., Shenzhen, China</p>	<p>MS27571</p>

ISSUE
<p>The HPRA has been informed by colleagues in Europe that the LOVEXOK One Step Pregnancy (HCG) Test Strip is non-compliant and does not bear a valid CE mark, as required in Europe. These tests are for detecting hCG (human Chorionic Gonadotropin) in urine to determine pregnancy. They either have no legal CE mark or bear a fake CE mark.</p>

ACTION OR RECOMMENDATIONS

The HPRA advises the public:

- 1 **Do not buy or use** the LOVEXOK One Step Pregnancy (HCG) Test Strips, either from websites or from any shop / supplier.
- 2 Contact your GP or pharmacist if you have (or think you may have) purchased or used a LOVEXOK One Step Pregnancy (HCG) Test Strip. If affected, consider the need to re-test.
- 3 Do not buy medical devices from websites that you have not verified.

The HPRA advises that healthcare professionals:

- 4 Notify the HPRA of any suspected or confirmed incidents of patients having purchased and/or used LOVEXOK One Step Pregnancy (HCG) Test Strips.
- 5 Advise affected patients of the need to re-test.

TARGET GROUPS

General public
General Practitioners
Pharmacies

Practice nurses
Purchasing managers
Community clinics

BACKGROUND

As these tests are non-compliant, they do not meet the necessary legal requirements for CE marking and there is no guarantee that they work properly. Therefore, someone who is not pregnant may get a false-positive result telling them they are pregnant. While, someone who is pregnant may get a false-negative test result making them think they are not pregnant. As a consequence, they may not get the necessary medical help recommended during pregnancy.

HPRA CONTACT INFORMATION

Questions about these devices or **adverse incidents** should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

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