

Safety Notice

Medical Devices

Freestyle Life Test Strips

Priority 2 – Warning



HPRA Safety Notice: SN2017(12)

Issue Date: 06 March 2017

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
PCO Manufacturing (supplier)	V30927

ISSUE

The HPRA has been informed by PCO Manufacturing that they have distributed Freestyle Lite Test Strips to the Irish market, the outer carton of which is not in the English language. PCO has advised that the instructions present on the vial and on the information leaflet contained within the packs are in English. These batches of test strips do not comply with the legislation for *in-vitro* diagnostic medical devices in Ireland.

PCO has issued a field safety notice (FSN) advising of the recall of affected batches.

ACTION OR RECOMMENDATIONS

The HPRA advises that healthcare professionals:

- (1) Ensure that relevant personnel receive a copy of the attached FSN.
- (2) Quarantine all affected product identified at your facility as soon as possible.
- (3) Acknowledge receipt of the FSN if you have not already done so.
- (4) Report any concerns regarding these devices to the manufacturer and the HPRA.

The HPRA advises that users:

- (1) Discontinue use of the affected batches of blood glucose test strips.
- (2) Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Pharmacists General public Diabetes clinics / outpatients	Diabetic Nurse Specialists Endocrinology Units Endocrinology Consultants
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BACKGROUND

PCO issued a FSN in February 2017 notifying customers that they have distributed Freestyle Lite Test Strips to the Irish market, the outer carton of which is not in the English language. PCO has indicated that the instructions on the vial and on the information leaflet contained within the packs are in English.

The affected products have been supplied to community pharmacies. Please refer to the accompanying FSN for further information.

The HPRA would also like to remind users of glucose test strips that the correct unit of measurement for blood glucose monitoring in Ireland is mmol/L.

DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **distributor** should be addressed to:

PCO Manufacturing Unit 10 Ashbourne Business Park Rath Ashbourne Co. Meath	Telephone: +353-1-8356700 E-mail: NClarke@pco.ie
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HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: devicesafety@hpra.ie Website: www.hpra.ie
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