

## MEDICAL DEVICES

# Self-Test Products

Many types of self-tests are now available. Self-tests that have a medical purpose are *in-vitro* diagnostic medical devices. They can be used to diagnose a variety of conditions or to monitor a particular treatment. They can be purchased from many different sources including pharmacies and supermarkets. While self-tests may have a role to play, they should not be relied upon on their own and it is important to remember that if you have any concerns about your health or a test result you should consult a healthcare professional.

## What are self-tests?

Self-tests are healthcare products or pieces of equipment that a person uses for a medical purpose at home. They come in a variety of forms; for example, a dipstick or a test strip that you insert into a meter. The type of sample needed to carry out the test can include blood, urine, stool or saliva. Some common examples include pregnancy tests and test kits for measuring blood sugar.

## Important things to note if you are thinking of self-testing

- No self-test is 100% reliable.
- Self-tests should not be relied upon on their own.
- A number of factors may interfere with or affect test results; for example, medicines and dietary supplements. You should always read the instructions carefully to see how your results might be impacted.
- If you have any concerns about your health you should consult your GP.

## If you are thinking of buying a self-test

- You should purchase from a reliable source.
- Make sure that the device has a CE mark. All valid medical devices must bear a CE mark for the specific medical purpose claimed.
- As well as the CE mark, self-testing devices must also have a four digit number to confirm that they meet important safety and design standards. This number will be displayed close to the CE mark.
- Look for a European address. Medical devices that are CE marked and sold on the European market must have a registered business premises in Europe.

**CE** A valid medical device bears a CE mark, which indicates that it meets the basic requirements for safety and effectiveness under European law.

## When using the test

- Make sure that the packaging is not damaged and check that seals are not broken.
- Check the expiry date on the packaging, do not use if it is out of date.
- Check if you need anything else before performing the test. For example, a stopwatch or water.
- Read the instructions carefully before performing the test.
- Make sure that you know how to interpret the test result.
- Make sure that you dispose of the test properly when you are finished.

## After using the test

- Remember no self-test is 100% reliable.
- Regardless of the result if you have concerns or your symptoms persist, consult your GP.

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## Buying a medical device online

Buying a test over the internet may give you privacy and save you money, but the risks associated with the device may be greater. While genuine tests are available online, some that are advertised may pose a threat to your health. Some tests may not work properly, may not be intended for your condition, may only be for use by healthcare professionals or may even be fake.

## How to report an incident to the HPRA

You should report any unexpected problem or malfunction that may affect your health or cause or contribute to an injury to your healthcare provider, the HPRA and the manufacturer of the device.

You can report incidents to the HPRA by filling in our online user report form on [www.hpra.ie](http://www.hpra.ie). If you would prefer to fill out a printed copy of the form, you can download it from our website or request a copy by phone or e-mail.

## More information

This is one in a series of information leaflets that you can get from the HPRA and from our website: [www.hpra.ie](http://www.hpra.ie).

## The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

### What does the HPRA do?

As the regulatory authority, we monitor the safety of all medical devices available in Ireland. Our aim is to make sure that these products do not compromise the health and safety of the patient or the person using them. We also work to ensure that medical device manufacturers comply with all safety regulations.

The HPRA cannot provide advice on which medical devices you should buy.



Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2  
Phone: (01) 676 4971  
Fax: (01) 634 4033  
E-mail: [devices@hpra.ie](mailto:devices@hpra.ie)

[www.hpra.ie](http://www.hpra.ie)



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